IN THE UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

PAULA DEATON and DONALD SHAFT, Plaintiffs, -vs- PFIZER, INC.; PHARMACIA CORPORATION; and G.D. SEARLE LLC (FKA G.D. SEARLE & CO.), Defendants.	)	Civil No. **JURY TRIAL DEMANDED**

COMPLAINT

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COMPLAINT

Plaintiffs, for their Complaint against Defendants, allege as follows:

I. INTRODUCTION.

1. This is a civil action seeking damages for personal injuries. The Plaintiffs assert product liability claims against Defendants PFIZER, INC., PHARMACIA CORPORATION; and G.D. SEARLE LLC (FKA G.D. SEARLE & CO.) (hereinafter referred to as "PFIZER") arising from the design, manufacture, and sale of a drug known as Celebrex ("CELEBREX"). It is alleged by the Plaintiffs that CELEBREX was a defective and unreasonably dangerous product that caused their damages.

2. It is anticipated that these actions will be subject to transfer and consolidation for pretrial proceedings pursuant to 28 U.S.C.A. §1407 in the United States District Court for the District of Minnesota. *See In Re Bextra and Celebrex Product Liability Litigation*, MDL 1699 (J.P.M.D.L., *filed* Sept. 6, 2005) (transfer order, attached as Exhibit "A"). Plaintiffs join their individual and several claims against Defendants into this one lawsuit because their claims arise out of the same transaction, occurrence, or series of transactions or occurrences and questions of law and fact common to all Plaintiffs will arise in this action. FED. R. CIV. P. 20(a). Joinder of these parties and claims for transfer and pretrial proceedings would work to "secure the just, speedy, and inexpensive determination of (this) action." FED. R. CIV. P. 1. Therefore, Plaintiffs have joined their claims in this Complaint.

II. THE PARTIES.

A. The Individual Plaintiffs.

3. Plaintiff, **PAULA DEATON**, is an adult individual residing in Tennessee.

4. Plaintiff, **DONALD SHAFT**, is an adult individual residing in Kansas.

B. The Defendants PFIZER, INC.; PHARMACIA CORPORATION; and G.D. SEARLE LLC (FKA G.D. SEARLE & CO.).

5. Defendant **PFIZER, INC.**, is a foreign, for-profit corporation. PFIZER is incorporated in Delaware and has its principal place of business in New York, New York. At all times material, PFIZER was and is in good standing and actively doing business in the State of Minnesota. On July 16, 2002, PFIZER announced its proposed acquisition of PHARMACIA CORPORATION ("PHARMACIA"). On April 16, 2003, PFIZER completed its $60 billion acquisition of PHARMACIA. As a wholly-owned subsidiary of PFIZER, PHARMACIA acted in all aspects as PFIZER's agent and alter ego. At all relevant times, PFIZER and/or its predecessors in interest were engaged in the business of designing, testing, manufacturing, packaging, marketing, distributing, promoting, and selling the drug Celecoxib under the trade name CELEBREX in Minnesota and throughout the United States.

6. Defendant **G.D. SEARLE LLC (FKA G.D. SEARLE & CO.)** ("SEARLE") is a Delaware corporation with its principal place of business in Illinois. In April 2000 SEARLE was acquired by PHARMACIA, and became a wholly-owned subsidiary of PHARMACIA. At the time of PFIZER's acquisition of PHARMACIA, SEARLE was a wholly-owned subsidiary of PHARMACIA, acting as its agent and alter ego in all matters alleged in this Complaint, and is now a wholly-owned subsidiary of PFIZER. At all relevant times, SEARLE has been engaged in the business of designing, testing, manufacturing, packaging, marketing, distributing, promoting, and selling the drug Celecoxib under the trade name CELEBREX in Minnesota and throughout the United States.

7. Defendant **PHARMACIA CORPORATION** is a Delaware corporation with its principal place of business in New Jersey. PHARMACIA was created in April 2000 through the merger of Pharmacia & Upjohn with Monsanto Company and its G.D. SEARLE unit.

PHARMACIA is now a wholly-owned subsidiary of PFIZER. At all relevant times, PHARMACIA, and its predecessors in interest have been engaged in the business of designing, testing, manufacturing, packaging, marketing, distributing, promoting, and selling the drug Celecoxib under the trade name CELEBREX in Minnesota and throughout the United States.

8. Celecoxib was developed in 1998 by SEARLE and marketed jointly by SEARLE and PFIZER under the brand name CELEBREX. SEARLE was acquired by PHARMACIA, which was then acquired by PFIZER, in part so that PFIZER could take full control of CELEBREX.

9. At all times relevant to this action, Defendants intentionally, recklessly and/or negligently concealed, suppressed, omitted, and misrepresented the risks, dangers, defects, and disadvantages of CELEBREX, and advertised, promoted, marketed, sold and distributed CELEBREX as a safe prescription medication when, in fact, Defendants had reason to know, and did know, that CELEBREX was not safe for its intended purposes, for the patients for whom it was prescribed, and for whom it was sold; and that CELEBREX caused serious medical problems, and in certain patients, catastrophic injuries and deaths.

10. In engaging in the conduct alleged herein, each Defendant acted as the agent for each of the other Defendants, or those Defendants' predecessors in interest.

III. JURISDICTION AND VENUE.

11. This Court has subject matter jurisdiction under 28 U.S.C.A. §1332 (diversity jurisdiction). Plaintiffs and PFIZER are citizens of different states and the amount in controversy exceeds Seventy-Five Thousand Dollars ($75,000.00).

12. This Court has personal jurisdiction over PFIZER who, at all times material, was and is licensed and registered to do business in Minnesota. PFIZER maintains a registered agent

for the service of process in Minnesota: CT Corporation System, Inc., 405 2nd Avenue South, Minneapolis, MN 55401. Plaintiffs, by bringing this action, submit to this Court's personal jurisdiction.

13. As this is a case is based upon diversity jurisdiction, this Court applies the forum state's choice-of-law rules. *Glover v. Merck & Co., Inc.*, 345 F.Supp.2d 994, 997 (D. Minn. 2004). Therefore, Minnesota choice-of-law principles apply here. *Id*

14. As it relates to statutes of limitation, the traditional rule in Minnesota is that such statutes are procedural and governed by the law of the forum. *Id*

15. Venue is proper in this District pursuant to 28 U.S.C.A. §1391. PFIZER marketed, advertised and distributed the dangerous product in this District, thereby receiving substantial financial benefit and profits from sales of the dangerous product in this District, and reside in this District under 28 U.S.C.A. §1391(c), such that venue is proper.

16. At all relevant times herein, PFIZER was in the business of designing, manufacturing, marketing, developing, testing, labeling, promoting, distributing, warranting and selling their product, CELEBREX. PFIZER at all times relevant hereto designed, developed, manufactured, promoted, marketed, distributed, tested, warranted and sold in interstate commerce (including Minnesota) the aforementioned prescription drug. PFIZER does substantial business in the State of Minnesota and within this District, advertises in this District, receives substantial compensation and profits from sales of CELEBREX in this District, and made material omissions and misrepresentations and breaches of warranties in this District so as to subject them to *in personam* jurisdiction in this District. In engaging in the conduct herein, each Defendant acted as the agent for each of the other Defendants or those Defendants' predecessors in interest.

IV. FACTS COMMON TO ALL PLAINTIFFS.

A. Facts Regarding CELEBREX: Science and Other COX-2 Inhibitors.

17. CELEBREX is among a class of pain medications called non-steroidal anti-inflammatory drugs ("NSAIDs"). Aspirin, naproxen (trade name Aleve®), and ibuprofen (trade name Advil®) are examples of well-known NSAIDs.

18. NSAIDs reduce pain and inflammation by blocking the body's production of pain transmission enzymes called cyclooxygenase, COX-1 and COX-2. COX enzymes trigger the sequential oxidation of various fatty acids to create prostaglandins. Prostaglandins are important cogs in the physiology of pain, igniting hormone-like actions in the immediate vicinity of the cells that release them, thereby inducing inflammation, pain, and fever.

19. Because COX enzymes and prostaglandins increase the pain associated with tissue injury, the synthesis of prostaglandins by cells of injured tissue becomes a reasonable target for pain-management drugs.

20. Traditional NSAIDs like aspirin, ibuprofen and naproxen inhibit both COX-1 and COX-2 enzymes simultaneously, providing relief from inflammation and pain, but at the cost of potential adverse gastrointestinal effects, as the prostaglandins that are supported by COX-1 enzymes are involved in the production of gastric mucus which protects the stomach wall from the hydrochloric acid present in the stomach. By blocking the COX-1 enzyme, the body's ability to protect gastric tissue is hampered and, as a result, can cause harmful gastrointestinal side effects, including stomach ulceration and bleeding.

21. PFIZER and other pharmaceutical companies set out to remedy these gastrointestinal side effects suffered by some NSAID users by developing "selective" inhibitors, called coxibs, which targeted only COX-2 production, thus (allegedly) allowing for proper

maintenance of gastric tissue while still reducing inflammation. Their development was based on the hypothesis that COX-2 was the source of prostaglandins E2 and I2, which mediate inflammation, and that COX-1 was the source of the same prostaglandins in the stomach lining. By not inhibiting COX-1, whose products provide cytoprotection in the gastric epithelium; these coxibs were thought to decrease the incidence of gastric side effects when compared to traditional NSAIDS that inhibit both COX-1 and COX-2.

22. In making this decision, however, PFIZER and their predecessors in interest either intentionally ignored and/or recklessly disregarded current medical knowledge that selective COX-2 inhibition lowers prostaglandin I2 levels, the predominant COX-2 product responsible for preventing platelet aggregation, clotting and vasoconstriction, while leaving thromboxane A2 (a potent COX-1 platelet aggregator and vasoconstrictor), unaffected. By selectively inhibiting COX-2 (prostaglandin I2) without similarly suppressing its COX-1 counterpart, CELEBREX and other coxibs expose their users to a host of clot-related cardiovascular risks, including heart attack, stroke, unstable angina and serious thromboembolic events.

23. On June 29, 1998, SEARLE and PFIZER filed for the U.S. Food and Drug Administration ("FDA") approval of Celecoxib, its first major COX-2 inhibitor drug, under the trade name CELEBREX. The FDA granted preliminary approval of the new drug on December 31, 1998 for the relief of signs and symptoms of adult osteoarthritis and rheumatoid arthritis. A year later, on December 23, 1999, the FDA granted accelerated approval of CELEBREX for a second indication; the reduction of intestinal polyps as an adjunct to endoscopy and surgery in patients with familial adenomatous polyposis (FAP), a rare genetic disorder.

24. In late January 1999, following FDA approval, PFIZER publicly launched CELEBREX, their new "blockbuster" drug, in one of the largest direct-to-consumer marketing campaigns ever undertaken for prescription drugs. PFIZER's massive marketing campaign fraudulently and misleadingly depicted CELEBREX as a much safer and more effective pain reliever than less inexpensive traditional NSAIDs. PFIZER and its representatives and agents misrepresented the safety profile of CELEBREX to consumers, the medical community, healthcare providers, and third party payors.

B. Facts Regarding CELEBREX's Safety and PFIZER's Knowledge Thereof.

25. The potential for cardiovascular risk of selective COX-2 inhibitors was known to PFIZER long before the FDA granted market approval in December 1998. By 1997, and prior to the submission of the New Drug Application (the "NDA") for CELEBREX, PFIZER was aware that, by selectively inhibiting only the COX-2 enzyme, CELEBREX altered the homeostatic balance between prostacylcin synthesis and thromboxane and thereby increased the prothrombotic effects of the drugs, causing blood clots to form in those who ingested it. *See* Topol, E.J., *et al.*, "*Risk of Cardiovascular Events Associated with Selective Cox-2 Inhibitors*," JAMA, August 22, 2001 at 954.

26. Pharmacologist Dr. Garrett Fitzgerald of the University of Pennsylvania reported in an editorial published in *The New England Journal of Medicine* on October 21, 2004, that contemporaneous with PFIZER's launch it was known that selective COX-2 inhibitors, such as CELEBREX, suppressed the formation of prostaglandin I-2 in healthy volunteers, inhibited platelet aggregation in vitro, and may predispose patients to myocardial infarction or thrombotic stroke. Fitzgerald, G.A., Patrono C., "*The Coxibs, Selective Inhibitors of Cyclooxygenase-2,*" N Engl J Med 2001;345:433-442.

27. Early FDA updates in March and April of 1999 similarly acknowledged this known risk, but noted, based upon PFIZER's representations, that CELEBREX "does not affect platelet aggregation (clumping), an important part of the blood clotting process." *See* FDA Updates, *"New Arthritis Drug May Have Fewer Side Effects,"* FDA Consumer March-April 1999.

28. Based on the studies performed on CELEBREX, other COX-2 inhibitors, and basic research on this type of selective inhibitor which had been widely conducted, PFIZER knew when CELEBREX was being developed and tested that selective COX-2 inhibitors posed serious cardiovascular risks for anyone who took them, and presented a specific additional threat to anyone with existing heart disease or cardiovascular risk factors.

29. Despite years of studies on selective COX-2 inhibitors, as well as the disturbing new studies specifically analyzing the risks of CELEBREX, PFIZER failed to take any action to protect the health and welfare of patients, opting instead to continue promoting the drug for sale even after the FDA's Drug Safety and Risk Management Advisory Committee and Arthritis Drug Advisory Committee meetings.

C. CELEBREX and COX-2 Studies Did Not Show CELEBREX to be Safe.

I. CELEBREX Long-Term Arthritis Safety Study (CLASS).

30. In September 1998, PHARMACIA sponsored an allegedly independent CELEBREX Long-Term Arthritis Safety Study ("CLASS") The multicenter, double-blind, parallel group study sought to compare the incidence of clinically significant upper gastrointestinal events between CELEBREX 400 mg BID and Ibuprofen 800 mg. (CLASS data is found in NDA 20-998/S-009 submitted to the FDA by SEARLE on June 12, 2000. CLASS

was submitted to the FDA on June 12, 2000 and reviewed by James Witter, M.D., Ph.D. (FDA Medical Officer) on September 20, 2000.)

31. On September 13, 2000, PFIZER released the results of the CLASS study in the *Journal of American Medicine*. Silverstein, F.E., *et al.*, "*Gastrointestinal Toxicity with Celecoxib vs. Nonsteroidal Anti-inflammatory Drugs for Osteoarthritis and Rheumatoid Arthritis. The CLASS Study: A Randomized Controlled Trial,*" 284 JAMA 1247 (2000). Researchers enthusiastically reported a "lower incidence of symptomatic ulcers and ulcer complications combined, as well as other clinically supported toxic effects, compared with NSAIDs at standard doses."

32. Although PFIZER touted the CLASS study as the primary evidence to support its theory that CELEBREX was safer for consumers who could not tolerate traditional NSAIDs in their gastrointestinal system, PFIZER intentionally, recklessly and/or negligently concealed, suppressed, omitted, and misrepresented the results, risks and defects of the CLASS study. Among other things, PFIZER failed to release the study's complete twelve month results-releasing only the first six months of trials, reported biased and misleading results, limited conclusions to upper gastrointestinal events despite other known risks factors, and understated known cardiovascular risks.

33. Despite PFIZER's favorable CLASS Study conclusions, no other reviewing or administrative body was able to substantiate those findings. The FDA Medical Officer Review of the CLASS data found CELEBREX to be no more efficacious than other traditional NSAIDS comparators. *See generally*, FDA Medical Officer Review, NDA 20-998/S-009 submitted to the FDA by SEARLE on June 12, 2000. According to the FDA's review of the CLASS data: "Celecoxib did not demonstrate any statistical superiority to NSAIDs (pooled) or either

comparator (diclofenac and ibuprofen) with regards to the primary safety endpoint of CSUGIE (Clinically Significant Upper Gastrointestinal Adverse Events) at any point in the trial although there were trends that favored celecoxib." (FDA CLASS Review).

34. The FDA Arthritis Advisory Committee similarly found no "clinically meaningful" safety advantage of CELEBREX over older NSAIDs. (FDA CDER Arthritis Advisory Committee, February 7th and 8th, 2001, Gaithersburg, Maryland). The CLASS Study failed to demonstrate a superior safety record over ibuprofen or pooled NSAID data. Based on this information, the Committee advised that further studies be done to assess the risk of COX-2 drugs and NSAIDS when taken with aspirin.

35. In a June 2002 editorial, the *British Medical Journal* chastised the Study's "misleading" and "seriously biased" nature; noting that the complete results "clearly contradict(ed) the published conclusions," and warning against the dangers of "overoptimistic," "short-term" data and "post hoc changes to the protocol." Juni, Peter, *et. at., "Are Selective COX 2 Inhibitors Superior to Traditional Non Steroidal Anti-Inflammatory Drugs?"* BMJ 2002;324:1287-1288. Most noticeably, the CLASS study considered only six months of data despite the fact that researchers at that point had 12 months of data that, when analyzed as a whole, showed no significant difference. Instead of releasing the complete 12-month results from CLASS, PFIZER relied on and published only the first six months of data. JAMA 2000, 48:1455-1460. The results of the completed study revealed the real truth: CELEBREX offered no gastrointestinal (GI) benefit. Almost all ulcer-related complications that had occurred during the second half of the CLASS trials were in users of CELEBREX. These results clearly contradict the published CLASS conclusions.

36. Editors of the Journal of the American Medical Association (JAMA) and other medical experts were reportedly "flabbergasted" when they realized they had been "duped" by only being provided with the first six months of CLASS data. Okie S., *"Missing data on Celebrex Full study altered picture of drug,"* Washington Post 2001 Aug 5;Sect A:11. The *Washington Post* reported JAMA editors noting: "When all of the data were considered, most of CELEBREX's apparent (GI) safety advantage disappeared."

37. Institutional bias also appeared to play a role in the Study's biased conclusions. According to the *Washington Post*, all sixteen CLASS authors were either employees of PHARMACIA or paid consultants of the company. Okie, S., *"Missing data on Celebrex Full study altered picture of drug,"* Washington Post 2001 Aug 5;Sect A:11. Moreover, at least one author, Dr. M. Michael Wolfe, a gastroenterologist from Boston University, admits he was duped by PHARMACIA. In the summer of 2000, *The Journal of the American Medical Association* asked Wolfe to participate in the "six-month" trial. Wolfe found the study, tracking 8,000 patients over a six-month period, persuasive, and penned a favorable review, which helped to drive up CELEBREX sales. It was not until early the next year, while serving on the FDA's Arthritis Advisory Committee, that Wolfe learned the study had run for one year, not six months, as the company had originally led both Wolfe and the *Journal* to believe. *Id* Here again, when the complete data was considered, most of CELEBREX's advantages disappeared.

38. PFIZER also limited conclusions of the CLASS study to upper gastrointestinal events, despite other known risks factors, and understated known cardiovascular risks. A metastudy by the Cleveland Clinic published in the Journal of the American Medical Association analyzed data from two major studies, including CLASS, funded by the drug companies and two smaller ones—all for cardiovascular risks. Debabrata Mukherjee, *et al*., "*Risk of Cardiovascular*

Events Associated with Selective Cox-2 Inhibitors," 286 JAMA 954 (2001).) The metastudy found that PHARMACIA failed to identify and study cardiovascular risks for their products. The annualized heart attack rates for patients taking Vioxx or CELEBREX, the researchers found, were "significantly higher" than those in a group taking placebos. "The available data raise a cautionary flag about the risk of cardiovascular events with Cox-2 inhibitors," they concluded.

39. "A total of 36 deaths occurred during the (CLASS) study or during post study follow-up: 19 in the celecoxib group, 9 in the diclofenac group and 8 in the ibuprofen group . . . . Most deaths were cardiovascular in nature." FDA CLASS Review at 54. The increased number of adverse cardiovascular events in the CELEBREX group was not surprising, as they were also revealed in the original New Drug Application (NDA) submitted for CELEBREX. "In the original NDA, myocardial infarction was noted to occur at a higher rate in celecoxib-treated as compared to placebo treated patients. In the long term trial (Trial 024) that was included in the NDA submission, the predominate (>90%) cause of death for patients taking celecoxib at any dose was cardiovascular." FDA CLASS Review at 78.

40. Public Citizen, a public watchdog organization, also reviewed the CLASS data in its entirety. A complete review reveals the combined anginal adverse events were 1.4% in the CELEBREX group versus 1.0% in either NSAID group. Specifically, the rate of heart attack in the CELEBREX was double that of the other two NSAIDs, 0.2% vs. 0.1%, respectively.

41. Eric Topol of the Cleveland Clinic reached a similar conclusion, noting that the CLASS trial MI rate was 1.6% in CELEBREX group (at a dosage of 400 mg twice a day) and 1.2% in the ibuprofen group for the 1739 patients taking low-dose aspirin. Topol noted that this numerical excess, albeit not statistically significant, was also found in the 6229 patients not taking aspirin in the trial. Eric J. Topol, *"Arthritis Medicines and Cardiovascular Events –*

House of Coxibs," JAMA 293:366. Based on this data, Topol and his colleagues concluded: "It is mandatory to conduct a trial specifically assessing cardiovascular morbidity." *Id.* Unfortunately, no such trials were ever initiated, delaying the official warnings of CELEBREX and jeopardizing countless lives in the process.

42. The CLASS data proves that PFIZER knew that its first generation COX-2 inhibitor, CELEBREX, caused a disproportionately and statistically significant high number of adverse cardiovascular events before it was introduced to the market in January 1999. According to Public Citizen, after CLASS, the FDA recommended a trial to specifically assess the cardiovascular risks of COX-2 inhibitors. The Adenoma Prevention with Celecoxib (APC) trial was intended to be this placebo-controlled trial of CELEBREX.

II. APC Trial.

43. In early 2000, the National Cancer Institute (NCI), in collaboration with SEARLE and PFIZER, initiated the Adenoma Prevention with Celecoxib (APC) trial, a randomized, double-blind, placebo-controlled study to discover the efficacy of CELEBREX in preventing the growth of pre-cancerous colon polyps. N.ENG. J. MED. 352;11 at 1072. The trial involved 2026 patients across the country with randomization to one of three groups: (1) placebo; (2) 200 mg CELEBREX twice daily; and (3) 400 mg CELEBREX twice daily. The patients, each of whom had an adenomatous polyp removed before enrollment, were followed up for a mean of 33 months while taking the study drug, with the primary objective of limiting the development of colorectal cancer.

44. On December 17, 2004, the National Cancer Institute suspended the use of CELEBREX for all participants in the APC trial due to "significant excess of cardiovascular death, myocardial infarction (MI) and stroke." Eric J. Topol, "*Arthritis Medicines and*

Cardiovascular Events – House of Coxibs," JAMA 293:366. Analysis by an independent Data Safety Monitoring Board (DSMB) showed a two to three fold increased risk of major fatal and non-fatal cardiovascular events for participants taking the drug compared to those on a placebo with a secondary dose-response effect.

45. The absolute excess of major cardiovascular events of 13/1000 patients at the 800 mg dose (400 mg 2x day) was strikingly similar to the results of trials with rofecoxib and valdecoxib, both selective NSAID COX-2 inhibitors removed for the market for their significant cardiovascular risks. Eric J. Topol, *"Arthritis Medicines and Cardiovascular Events – House of Coxibs,"* JAMA 293:366.

46. The FDA reported similar results, noting:

> In the National Cancer Institute's Adenoma Prevention with Celecoxib (APC) trial in patients at risk for recurrent colon polyps, a 2-3 fold increased risk of serious adverse CV events was seen for CELEBREX compared to placebo after a mean duration of treatment of 33 months. There appeared to be a dose response relationship, with a hazard ratio of 2.5 for CELEBREX 200 mg twice daily and 3.4 CELEBREX 400 mg twice daily for the composite endpoint of death from CV causes, myocardial infarction (MI), or stroke.

April 7, 2005 FDA Alert: www.fda.gov/cder/drug/infopage/celebrex/celebrex-hcp.htm.

47. The dosage noted in the study is itself important for two reasons: first, there appears to be an association between dosage and the increase in adverse cardiovascular events; second, most patients increase dosage. PFIZER knew patients were increasing their dosages as noted in the CLASS Study: "Interestingly ... up to 70% of patients increased their dose for celecoxib." FDA CLASS Review at 74. Thus, PFIZER was aware of "dosage creep."

III. Other CELEBREX Trials.

48. Several other CELEBREX trials also gave PFIZER insight into the cardiovascular risks presented by CELEBREX. The Prevention of Spontaneous Adenomatous Polyps (PreSAP)

trial identified the death rate from cardiovascular causes (heart attack, stroke, heart failure, angina, or need for CV procedure) as 3.6% with CELEBREX as compared to 2.7% for placebo.

49. Public Citizen also reviewed the results of Study IQ IQ5-97-02-001 which reflected "the combined rate of all serious cardiovascular adverse events in patients getting a placebo was 2.1% but was greatly increased in those getting celecoxib to 7.7%, a 3.6 fold increase in CV risk in those people taking celecoxib. (p=0.03)." *Public Citizen*, January 26, 2005, Dr. Sidney M. Wolfe. According to Dr. Sidney Wolfe, "The study revealed a significantly increased rate (3.6-fold) of serious CV adverse events and more than a doubling in the rate of CV deaths in people using celecoxib compared to those using placebo." Id.

IV. COX-2 Studies: VIGOR and APPROVe.

50. PFIZER also had access to other data which indicated a cardiovascular risk with its drugs. Specifically, PFIZER had knowledge of two studies conducted by Merck related to its COX-2 inhibitor Vioxx – Vioxx Gastrointestinal Outcomes Research (VIGOR) and Adenomatous Polyp Prevention (APPROVe).

a. VIGOR.

51. In 2000, The FDA Medical Officer Review of CLASS specifically noted the VIGOR trial and the concern over serious adverse cardiovascular events. FDA CLASS Review at 78.

52. According to VIGOR (near acronym for Vioxx Gastrointestinal Outcomes Research) Vioxx patients experienced 20% more serious clinical adverse events (statistically significant); they experienced 4.6 times more hypertension events serious enough to warrant discontinuation, 1.7 times more edema events, and 1.85 times as many congestive heart failure

adverse events. By two measures of cardiovascular events related to blood clots, Vioxx had twice the risk of naproxen and the results were considered statistically significant.

53. The VIGOR study comprised the most definitive scientific evidence ever obtained about pharmaceutical products. It was a large, randomized clinical trial, the gold standard of medical research. It was a safety study with endpoints set in advance. As Merck stated many times, it was designed to provide definite proof of safety, convincing enough to silence the most skeptical critics. In medical terms, the VIGOR results raised the question of whether selective inhibition of COX-2 was a monumental mistake from the start. While the NSAID risks to the GI system were real and sometimes fatal, they were dwarfed by the cardiovascular risks of the arthritis population that needed these drugs on a daily basis. All makers of NSAIDs, including PFIZER, were aware of these results.

b. APPROVe.

54. Anxious to put safety questions surrounding Vioxx to rest, Merck designed another large scale trial, Adenomatous Polyp Prevention (APPROVe), which was intended to test the drug's ability to prevent or shrink colon polyps, but would also compare the cardiovascular safety of Vioxx to a placebo control. According to the analysis conducted by Public Citizen of the APPROVe data: Vioxx "doubled the risk of any thrombotic cardiovascular event" and "doubled the risk of MI (myocardial infarction a/k/a heart attack)"[1]. *Public Citizen*, January 24, 2005, at 15. Despite the available CELEBREX data and other information related to Vioxx, PFIZER never paused to reevaluate the CELEBREX data and studies.

[1] Although Merck claims that the two-fold risk of heart attacks and strokes seen in the APPROVe trial did not emerge until after patients had been taking the drug for 18 months, closer analysis indicates that significant increase in risk of heart attack was evident in as little as 4 months time.

55. The scientific data available during and after CELEBREX's approval process made clear to PFIZER that their formulation of CELEBREX would cause a higher risk of blood clots, stroke and/or myocardial infarctions among CELEBREX consumers, alerting them to the need to do additional and adequate safety studies.

56. As stated by Dr. Topol on October 21, 2004, in *The New England Journal of Medicine*, outlining PFIZER's failure to have conducted the necessary trials before marketing to humans "it is mandatory to conduct a trial specifically assessing cardiovascular risk and benefit of (COX-2 inhibitors). Such a trial needed to be conducted in patients with established coronary artery disease, who frequently have coexisting osteoarthritis requiring medication and have the highest risk of further cardiovascular events."

57. Dr. Topol was also the author on the study published in August 2001 in JAMA (listed above) that reported an increased risk of thrombotic cardiovascular events in persons who used COX-2 inhibitors.

58. Based upon readily available scientific data, PFIZER knew, or should have known, that their pre-approval testing of CELEBREX did not adequately represent the cross-section of individuals who were intended consumers and therefore, likely to take CELEBREX. Therefore, PFIZER's testing and studies were grossly inadequate.

59. Had PFIZER done adequate testing prior to approval and market launch, rather than the extremely short duration studies done on the small size patient base that was actually done, the PFIZER's scientific data would have revealed significant increases in incidence of strokes and myocardial infarctions among the intended and targeted population of CELEBREX consumers. Adequate testing would have shown that CELEBREX possessed serious side effects. PFIZER should have taken appropriate measures to ensure that their defectively designed

product would not be placed in the stream of commerce and/or should have provided full and proper warnings accurately and fully reflecting the scope and severity of symptoms of those side effects should have been made.

60. In fact, post-market approval data did reveal increased risks of clotting, stroke and myocardial infarction, but PFIZER intentionally suppressed this information in order for them to gain significant profits from continued CELEBREX sales.

61. PFIZER's failure to conduct adequate testing and/or additional testing prior to market launch was based upon their desire to generate maximum financial gains for themselves and to gain a significant market share in the lucrative multi-billion dollar COX-2 inhibitor market.

62. At the time PFIZER manufactured, advertised, and distributed CELEBREX to consumers, PFIZER intentionally or recklessly ignored and/or withheld information regarding the increased risks of hypertension, stroke, serious thromboembolic events and/or myocardial infarctions because PFIZER knew that if such increased risks were disclosed, consumers would not purchase CELEBREX, but instead would purchase other cheaper and safer NSAIDs.

D. Facts Regarding PFIZER's Marketing and Sale of CELEBREX.

63. Such an ineffective and unreasonably dangerous drug could only be widely prescribed as a result of a tremendous marketing campaign. In addition to being aggressive, the PFIZER's marketing campaign was fraudulent and misleading. But for fraudulent and misleading advertising, consumers, including the Plaintiffs, would not have purchased CELEBREX, a more costly prescriptive drug, ineffective for its intended purposes.

64. PFIZER's marketing was so fraudulent that the FDA issued three Warning Letters to PFIZER in October 1999, April 2000, and November 2000, all finding that PFIZER was

unlawfully making false or misleading statements concerning the safety and/or efficacy of CELEBREX. The November letter cited two direct-to-consumer television advertisements that overstated the efficacy of CELEBREX. The FDA ordered that SEARLE immediately cease distribution of the misleading ads.

65. On February 2001, the FDA issued a Warning Letter to PHARMACIA stating that promotional activities from marketing CELEBREX were unlawful because they were "false, lacking in fair balance, or otherwise misleading." The FDA found that CELEBREX had been promoted for unapproved uses, in unapproved dosing regiments, and that the marketers had made unsupportable claims that CELEBREX was safer and more effective than other NSAIDs.

66. In August 2001, it was revealed that PHARMACIA had misrepresented the results of a post-marketing clinical study of CELEBREX when submitting it for publication. PHARMACIA selectively omitted portions of the data relating to adverse effects. The *Washington Post* reported on August 5, 2001 that, "the study had lasted a year, not six months as . . . thought. Almost all of the ulcer complications that occurred during the second half of the study were in CELEBREX users. When all of the data were considered, most of CELEBREX's apparent safety advantage (as compared to traditional NSAIDs) disappeared."

67. On January 10, 2005 the FDA again issued PFIZER a written reprimand for its promotional activities. The reprimand reads: "These five promotional pieces (3 CELEBREX and 2 CELEBREX) variously: omit material facts … and make misleading safety, unsubstantiated superiority, and unsubstantiated effectiveness claims." Amid continued frustration with PFIZER's continually misleading marketing strategy and ever surmounting evidence of cardiovascular dangers, the FDA Advisory Panel voted overwhelmingly that the company should never again advertise the drug (CELEBREX).

68. At all times relevant herein, PFIZER engaged in a marketing campaign with the intent that consumers would perceive CELEBREX as a safer and better drug than its other NSAIDs and, therefore, purchase CELEBREX.

69. PFIZER widely and successfully marketed CELEBREX throughout the United States by, among other things, conducting promotional campaigns that misrepresented the efficacy of CELEBREX in order to induce a widespread use and consumption. CELEBREX was represented to aid the pain and discomfort of arthritis, osteoarthritis, and related problems PFIZER made misrepresentations by means of media advertisements, and statements contained in sales literature provided to Plaintiffs' prescribing physicians.

70. Despite knowledge of the dangers presented by CELEBREX, PFIZER and PFIZER's predecessors in interest, through their officers, directors and managing agents for the purpose of increasing sales and enhancing its profits, knowingly and deliberately failed to remedy the known defects of CELEBREX and failed to warn the public, including Plaintiffs, of the serious risk of injury occasioned by the defects inherent in CELEBREX. PFIZER and its officers, agents and managers intentionally proceeded with the inadequate safety testing, and then the manufacturing, sale and marketing of CELEBREX, knowing that persons would be exposed to serious potential danger, in order to advance their own pecuniary interests. PFIZER's conduct was wanton and willful, and displayed a conscious disregard for the safety of the public and particularly of Plaintiffs.

71. In an elaborate and sophisticated manner, PFIZER aggressively marketed CELEBREX directly to consumers and medical professionals (including physicians and leading medical scholars) in order to leverage pressure on third party payors, medical care organizations, and large institutional buyers (*e g*, hospitals) to include CELEBREX on their formularies.

Faced with the increased demand for the drug by consumers and health care professionals that resulted from PFIZER's successful advertising and marketing blitz, third party payors were compelled to add CELEBREX to their formularies. PFIZER's marketing campaign specifically targeted third party payors, physicians, and consumers, and was designed to convince them of both the therapeutic and economic value of CELEBREX.

72. PFIZER represented that CELEBREX was similar to ibuprofen and naproxen but was superior because it lacked any of the common gastrointestinal adverse side effects associated with these and other non-steroidal anti-inflammatory drugs ("NSAIDS"). PFIZER promoted CELEBREX as a safe and effective alternative that would not have the same deleterious and painful impact on the gut, but that would be just as effective, if not more so, for pain relief.

73. Yet, CELEBREX possessed dangerous and concealed or undisclosed side effects, including the increased risk of serious cardiovascular events, such as heart attacks, unstable angina, myocardial infarctions (heart attacks), deep vein thrombosis, pulmonary emboli, hypertension, and cerebrovascular events, such as strokes. In addition, CELEBREX is significantly more expensive than traditional NSAIDs (costing $3.00 to $6.00 per day for CELEBREX versus $0.50/day for over the counter NSAIDs). Moreover, CELEBREX was no more effective than traditional and less expensive NSAIDs and, just like traditional NSAIDs, carried a risk of perforations, ulcers, and gastrointestinal bleeding. Yet, PFIZER chose not to warn about these risks and dangers.

74. PFIZER knew of these risks before the FDA approved CELEBREX for sale, but PFIZER ignored, downplayed, suppressed, omitted, and concealed these serious safety risks and denied the lack of efficacy in its promotion, advertising, marketing, and sale of CELEBREX. PFIZER's omission, suppression, and concealment of this important information enabled

CELEBREX to be sold to, and purchased, or paid for by, the Consumers at a grossly inflated price.

75. Consequently, CELEBREX captured a large market share of anti-inflammatory drugs prescribed for and used by patients. In 2004 alone, sales of CELEBREX exceeded $2 billion, despite the significantly higher cost of CELEBREX as compared to other pain relievers in the same family of drugs.

76. Because PFIZER engaged in a promotional and marketing campaign that featured an advertising blitz directly targeted to consumers, that touted CELEBREX as a safer drug than other drugs in its class, while uniformly failing to disclose the health risks of CELEBREX, PFIZER was able to justify pricing CELEBREX significantly higher than the cost of generic aspirin. In reality, that price inflation was not justified. Had PFIZER disclosed the truth about CELEBREX, PFIZER would not and could not have reaped the billions of dollars in CELEBREX sales that were achieved as a direct result of the concealment, omission, suppression, and obfuscation of the truth.

77. PFIZER intentionally, deliberately, knowingly, and actively concealed, omitted, suppressed, and obfuscated important and material information regarding the risks, dangers, defects, and disadvantages of CELEBREX from Plaintiffs, the public, the medical community, and the regulators. This concealment and omission was deliberate, knowing, active, and uniform, was intended to induce and maximize sales and purchases of CELEBREX, and prevented Plaintiffs from obtaining all the material information that would be important to their decision as a reasonable person to purchase, pay for, and/or use CELEBREX.

78. PFIZER's systematic, active, knowing, deliberate, and uniform concealment, omissions, suppression, and conduct caused Plaintiffs to purchase, pay for, and/or use CELEBREX; and caused Plaintiffs' losses and damages as asserted herein.

79. Had PFIZER done adequate testing prior to approval and "market launch," the PFIZER's scientific data would have revealed significant increases in stroke and myocardial infarction amongst the intended population of CELEBREX consumers. Adequate testing would have shown that CELEBREX possessed serious side effects. PFIZER should have taken appropriate measures to ensure that their defectively designed product would not be placed in the stream of commerce and/or should have provided full and proper warnings accurately and fully reflecting the scope and severity of symptoms of those side effects should have been made.

80. In fact, post-market approval data did reveal increased risks of clotting, stroke and myocardial infarction, but PFIZER intentionally suppressed this information in order for them to gain significant profits from continued CELEBREX sales.

81. PFIZER's failure to conduct adequate testing and/or additional testing prior to "market launch," and active concealment and failure to warn the medical community and general public of the known cardiovascular risks of CELEBREX was particularly negligent, reckless and/or malicious given the drug's known target market. PFIZER was well aware that most patients taking CELEBREX are elderly and have higher risk of developing cardiovascular risks to begin with. Nearly half of the patients with arthritis have coexisting cardiovascular disease, and most patients, as discovered in the CLASS study, were prone to higher dosing.

82. PFIZER's failure to conduct adequate testing and/or additional testing prior to "market launch" was based upon their desire to generate maximum financial gains for

themselves and to gain a significant market share in the lucrative multi-billion dollar COX-2 inhibitor market.

83. At the time PFIZER manufactured, advertised, and distributed CELEBREX to consumers including Plaintiffs, PFIZER intentionally or recklessly ignored and/or withheld information regarding the increased risks of hypertension, serious thromboembolic events, stroke and/or myocardial infarctions because PFIZER knew that if such increased risks were disclosed, consumers would not purchase CELEBREX, but instead would purchase other cheaper and safer NSAID drugs.

V. INDIVIDUAL PLAINTIFF'S STATEMENT OF FACTS.

A. PLAINTIFF PAULA DEATON:

84. Plaintiff **PAULA DEATON** was prescribed CELEBREX on June 6, 2002. She took it daily and was still taking it on August 3, 2003, approximately fourteen months, at which time she was admitted to the hospital with chest pain she had had for two weeks prior to admission. She underwent cardiac catheterization and was diagnosed with ischemic heart disease. Plaintiff alleges that CELEBREX caused or contributed to cause Plaintiff's ischemic heart disease along with the resulting other injuries and damages.

85. Ms. Deaton and her healthcare providers were at the time of her injuries unaware and could not have reasonably known or have learned through reasonable diligence that such injuries directly resulted from Plaintiff's ingestion of CELEBREX. Plaintiff and her healthcare providers never knew of the significant increased risks of heart attacks or strokes caused by CELEBREX until various information was released sometime thereafter.

86. As a result of PFIZER's wrongful acts, Ms. Deaton suffered severe and permanent personal injuries as described above, as a result of her prescribed consumption of CELEBREX.

As a result of the severe and permanent personal injuries as described above, Ms. Deaton incurred and will continue to incur damages, including but not limited to, medical expenses and other economic losses. Additionally, Ms. Deaton has endured and will continue to endure pain, suffering, disability, mental anguish, and disfigurement, causing additional damages. These damages exceed $75,000.00

B. PLAINTIFF DONALD SHAFT:

87. Plaintiff **DONALD SHAFT** was prescribed CELEBREX on March 27, 1999. He took it daily and was still taking it on November 1, 2003, approximately four and one-half years, at which time he was admitted to the hospital for an acute inferior wall myocardial infarction (heart attack) followed by cardiac catheterization and five vessel coronary artery bypass surgery. Plaintiff alleges that CELEBREX caused or contributed to cause Plaintiff's heart attack along with the resulting other injuries and damages.

88. Mr. Shaft and his healthcare providers were at the time of his injuries unaware and could not have reasonably known or have learned through reasonable diligence that such injuries directly resulted from Plaintiff's ingestion of CELEBREX. Plaintiff and his healthcare providers never knew of the significant increased risks of heart attacks or strokes caused by CELEBREX until various information was released sometime thereafter.

89. As a result of PFIZER's wrongful acts, Mr. Shaft suffered severe and permanent personal injuries as described above, as a result of his prescribed consumption of CELEBREX. As a result of the severe and permanent personal injuries as described above, Mr. Shaft incurred and will continue to incur damages, including but not limited to, medical expenses and other economic losses. Additionally, Mr. Shaft has endured and will continue to endure pain,

suffering, disability, mental anguish, and disfigurement, causing additional damages. These damages exceed $75,000.00.

VI. CLAIMS FOR RELIEF.

A. Count I: Strict Liability.

90. Plaintiffs adopt by reference Paragraphs 1 through 89.

91. PFIZER and its predecessors in interest were engaged in the business of researching, designing, producing, manufacturing, testing, inspecting, packaging, advertising, promoting, selling, and distributing drugs and pharmaceutical products, particularly including CELEBREX as described above.

92. CELEBREX was and is defective and unreasonably dangerous to persons, like Plaintiffs herein, who might be expected to use the products. CELEBREX was in a defective condition because it was unsafe for normal or anticipated handling and consumption. CELEBREX was unreasonably dangerous as the product was dangerous to an extent beyond that which would be contemplated by the ordinary consumer, like Plaintiffs herein, who purchased it and used it, with the ordinary knowledge common to the community as to its characteristics. CELEBREX was also unreasonably dangerous because the drug, due to its dangerous condition, would not be put on the market by a reasonably prudent manufacturer or seller assuming they knew of its dangerous condition. CELEBREX was defective and unreasonably dangerous in design, manufacturing, instructions, and warnings.

93. CELEBREX was defective and unreasonably dangerous at the time the product left PFIZER's control.

94. CELEBREX was expected to reach and did reach Plaintiffs without substantial change in the condition in which the products were manufactured and sold.

95. The defects in CELEBREX and PFIZER's other wrongful acts caused or contributed to cause Plaintiffs' injuries and damages as set forth above.

96. WHEREFORE, Plaintiffs individually demand and pray for judgment against PFIZER, in an amount exceeding $75,000.00 with such other and further relief as the Court may deem just and equitable.

B. Count II: Breach of Implied Warranty of Merchantability.

97. Plaintiffs adopt by reference Paragraphs 1 through 98.

98. PFIZER and its predecessors are merchants as to its drugs and pharmaceutical products, particularly including CELEBREX described above. CELEBREX and other drugs and pharmaceutical products are goods.

99. PFIZER, as a merchant, impliedly warranted the merchantability of its drugs and pharmaceutical products, including CELEBREX.

100. CELEBREX was not merchantable as impliedly warranted. Specifically, but not exclusively, CELEBREX was not fit for the ordinary purposes for which it was used because: (1) it caused increased risk of serious thromboembolie, cardiovascular and cerebrovascular adverse events, including heart attacks, strokes, and other serious and harmful adverse health effects, and (2) was not effective in decreasing gastrointestinal side effects.

101. Plaintiffs, as consumers of CELEBREX, were reasonably expected to use, consume and/or be affected by CELEBREX.

102. PFIZER's breach of warranty and other wrongful acts caused or contributed to cause Plaintiffs' injuries and damages as set forth above.

103. WHEREFORE, Plaintiffs individually demand and pray for judgment against PFIZER, in an amount exceeding $75,000.00 with such other and further relief as the Court may deem just and equitable.

C. Count III: Breach of Implied Warranty of Fitness for a Particular Purpose.

104. Plaintiffs adopt by reference Paragraphs 1 through 103.

105. PFIZER and its predecessors, as merchants and sellers of drugs and pharmaceutical products, including CELEBREX as described above, knew or had reason to know of the particular purpose for which its goods were used.

106. The buyer of CELEBREX relied upon PFIZER's skill and judgment to select and furnish suitable products and goods.

107. As a result, an implied warranty of fitness for a particular purpose existed as to CELEBREX.

108. CELEBREX was not fit for its particular purpose because: (1) it caused increased risk of serious thromboembolie, cardiovascular and cerebrovascular adverse events, including heart attacks, strokes, and other serious and harmful adverse health effects, and (2) was not effective in decreasing gastrointestinal side effects.

109. CELEBREX was not fit for its particular purpose as impliedly warranted causing PFIZER to breach its implied warranty.

110. Plaintiffs, as consumers of CELEBREX, were reasonably expected to use, consume and/or be affected by CELEBREX.

111. PFIZER's breach of warranty and other wrongful acts caused or contributed to cause Plaintiffs' injuries and damages as set forth above.

112. WHEREFORE, Plaintiffs individually demand and pray for judgment against PFIZER, in an amount exceeding $75,000.00 with such other and further relief as the Court may deem just and equitable.

D. Count IV: Breach of Express Warranty.

113. Plaintiffs adopt by reference Paragraphs 1 through 112.

114. PFIZER expressly represented to Plaintiffs and other consumers and the medical community that CELEBREX was safe and fit for its intended purposes, that it was of merchantable quality, that it did not produce any dangerous cardiovascular or other side effects, particularly any unwarned-of side effects, and that it was adequately tested.

1) These warranties came in the form of:

a. PFIZER's public written and verbal assurances of the safety and efficacy of CELEBREX;

b. Press releases, interviews and dissemination via the media of promotional information, the sole purpose of which was to create an increased demand for CELEBREX, which failed to warn of the risk of injuries inherent to the ingestion of CELEBREX, especially to the long-term ingestion of CELEBREX;

c. Verbal and written assurances made by PFIZER regarding CELEBREX and downplaying the risk of injuries associated with the drug;

d. False and misleading written information, supplied by PFIZER, and published in the Physician's Desk Reference on an annual basis, upon which physicians relied in prescribing CELEBREX during the period of Plaintiffs' ingestion of CELEBREX, and;

e. advertisements.

2) The documents referred to above were created by and at the direction of PFIZER.

3) PFIZER knew or had reason to know that CELEBREX did not conform to these express representations in that CELEBREX is neither as safe nor as effective as represented, and that CELEBREX produces serious adverse side effects.

4) CELEBREX did not and does not conform to PFIZER's express representations because it is not safe, has numerous and serious side effects, including unwarned-of side effects, and causes severe and permanent injuries.

5) Plaintiffs, other consumers, and the medical community relied upon PFIZER's express warranties.

6) PFIZER's breach of express warranty and other wrongful acts caused or contributed to cause Plaintiffs' injuries and damages as set forth above.

115. WHEREFORE, Plaintiffs individually demand and pray for judgment against PFIZER, in an amount exceeding $75,000.00 with such other and further relief as the Court may deem just and equitable.

E. Count V: Negligence.

116. Plaintiffs adopt by reference Paragraphs 1 through 115.

117. PFIZER and its predecessors were negligent in preparing, designing, researching, developing, producing, manufacturing, testing, inspecting, packaging, advertising, promoting, selling, and/or distributing CELEBREX. PFIZER's negligence included, but is not limited to, the following:

a. PFIZER negligently failed to provide any or adequate and proper warnings as to the dangers of the use of CELEBREX for persons who were reasonably and foreseeably expected to use CELEBREX, such as Plaintiffs named herein;

b. PFIZER negligently failed to warn and failed to provide adequate instructions for the use of CELEBREX for persons who were reasonably and foreseeably expected to use CELEBREX, such as Plaintiffs herein;

c. PFIZER negligently failed to investigate, perform adequate research and/or test for the hazards of CELEBREX;

d. To the extent that PFIZER may have inquired as to the hazards of CELEBREX, PFIZER negligently failed to convey whatever knowledge or dangers, health hazards, or safety precautions it may have had to the prescribers, users and consumers of CELEBREX;

e. PFIZER negligently failed to include adequate warnings with the drug that would alert the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiffs, to the potential risks and serious side effects of the drug;

f. PFIZER negligently failed to adequately and properly test and inspect the drug before placing the drug on the market;

g. PFIZER negligently failed to conduct sufficient testing and inspection of the drug which, if properly performed, would have shown that the drug had serious side effects, including but not limited to, an increased risk of adverse cardiovascular events and/or death;

h. PFIZER negligently failed to adequately warn the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiffs, of the potential risks and other serious side effects associated with the drug, including but not limited to an increased risk of serious thromboembolic and cardiovascular events and/or death;

i. PFIZER negligently failed to conduct adequate pre-clinical testing and research to determine the safety of CELEBREX;

j. PFIZER failed to conduct adequate post-marketing surveillance and exposure studies to determine the safety of CELEBREX;

k. PFIZER negligently failed to provide adequate post-marketing warnings or instructions after PFIZER knew, or should have known, of the significant risks associated with the use of the drug;

l. PFIZER negligently failed to recall and/or remove the drug from the stream of commerce despite the fact that PFIZER knew, or should have known, of the defective and unreasonably dangerous nature of the drug, including the significant health risks associated with the use of the drug; and

m. PFIZER negligently encouraged the misuse and overuse of CELEBREX while failing to disclose the side effects of the drug to the medical, pharmaceutical and/or scientific communities, and users and/or consumers, including Plaintiffs, in order to make a profit from sales.

118. PFIZER's negligence and other wrongful acts caused or contributed to cause Plaintiffs' injuries and damages as set forth above.

119. WHEREFORE, Plaintiffs individually demand and pray for judgment against PFIZER, in an amount exceeding $75,000.00 with such other and further relief as the Court may deem just and equitable.

VIII. DEMAND FOR JUDGMENT AGAINST DEFENDANTS PFIZER, INC.; PHARMACIA CORPORATION; and G.D. SEARLE LLC (FKA G.D. SEARLE & CO.).

WHEREFORE, Plaintiffs, Paula Deaton and Donald Shaft, individually demand judgment of and from PFIZER in an amount in excess of $75,000.00, and seek compensatory damages together with interest, cost of suit and attorney fees and for such other and further relief as the Court deems just and equitable.

VIII. DEMAND FOR JURY TRIAL.

Plaintiffs demand a trial by jury on all claims so triable in this action.

Respectfully submitted,

Dated: June 15, 2007

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Attorneys for Plaintiffs

JS 44 (Rev. 11/04)

CIVIL COVER SHEET

The JS-44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS

PAULA DEATON and DONALD SHAFT

(b) County of Residence of First Listed Plaintiff State of Tennessee
(EXCEPT IN U.S. PLAINTIFF CASES)

DEFENDANTS

Pfizer, Inc., a Delaware Corporation; Pharmacia Corporation, a Delaware Corporation; and G.D. Searle LLC, a Delaware Corporation

County of Residence of First Listed Defendant AGENT FOR SERVICE OF PROCESS IN MPLS., MN
(IN U.S. PLAINTIFF CASES ONLY)

(c) Attorney's (Firm Name, Address, and Telephone Number)
Martha K. Wivell, Esq., #0128090
Suite 1025 Fifth Street, 100 South Fifth Street
Minneapolis, MN 55402
Telephone: (612) 767-7500

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☒ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal

PERSONAL INJURY
- ☐ 362 Personal Injury—Med. Malpractice
- ☒ 365 Personal Injury — Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

FORFEITURE/PENALTY
- ☐ 610 Agriculture
- ☐ 620 Other Food & Drug
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 630 Liquor Laws
- ☐ 640 R.R. & Truck
- ☐ 650 Airline Regs.
- ☐ 660 Occupational Safety/Health
- ☐ 690 Other

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt Relations
- ☐ 730 Labor/Mgmt Reporting & Disclosure Act
- ☐ 740 Railway Labor Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc. Security Act

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce/ICC Rates/etc.
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 810 Selective Service
- ☐ 850 Securities/Commodities Exchange
- ☐ 875 Customer Challenge 12 USC 3410
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 892 Economic Stabilization Act
- ☐ 893 Environmental Matters
- ☐ 894 Energy Allocation Act
- ☐ 895 Freedom of Information Act
- ☐ 900 Appeal of Fee Determination Under Equal Access to Justice
- ☐ 950 Constitutionality of State Statues

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

CIVIL RIGHTS
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 444 Welfare
- ☐ 445 Amer. w/ Disabilities Employment
- ☐ 446 Amer. w/ Disabilities – Other
- ☐ 440 Other Civil Rights

PRISONER PETITIONS
- ☐ 510 Motions to Vacate Sentence
- Habeas Corpus:
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition

V. ORIGIN (PLACE AN "X" IN ONE BOX ONLY)

☒ 1 Original Proceeding | ☐ 2 Removed from State Court | ☐ 3 Remanded from Appellate Court | ☐ 4 Reinstated or Reopened | ☐ 5 Transferred from another district (specify) | ☐ 6 Multidistrict Litigation | ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION (Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity): 28 U.S.C. Section 1332
Brief description of cause: Products Liability

VII. REQUESTED IN COMPLAINT: ☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23 | DEMAND $ In excess of $75,000 | CHECK YES only if demanded in complaint: JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY (See instructions): MDL 1699 Northern District of California
JUDGE | DOCKET NUMBER MDL 1699

DATE 06/13/07

SIGNATURE OF ATTORNEY OF RECORD Martha K. Wivell

FOR OFFICE USE ONLY
RECEIPT # | AMOUNT | APPLYING IFP | JUDGE | MAG. JUDGE

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Paula Deaton and Donald Shaft,

Plaintiffs,

vs.

Pfizer, Inc.; Pharmacia Corporation; and G.D. Searle LLC, (FKA F.D. Searle & Co.),

Defendants.

Court File No. **07-2800** RHK/AJB

ANSWER AND DEFENSES OF DEFENDANTS PFIZER INC., PHARMACIA CORPORATION, AND G.D. SEARLE LLC TO PLAINTIFFS' COMPLAINT

Defendants Pfizer Inc., improperly captioned "Pfizer, Inc." (hereinafter "Pfizer"), Pharmacia Corporation (hereinafter "Pharmacia"), and G.D. Searle LLC (hereinafter "Searle"), collectively "Defendants," hereby answer Plaintiffs' Complaint in this action as follows:

Defendants' Answer And Affirmative Defenses To Plaintiffs' Complaint

1. Answering paragraph 1, Defendants state that the allegations contained therein assert legal conclusions to which no response is required. To the extent a response is deemed required, Defendants deny the allegations contained therein and specifically deny that Celebrex® is or was defective of unreasonably dangerous.

2. Answering paragraph 2, Defendants state that the allegations contained therein assert legal conclusions to which no response is required. To the extent a response is deemed required, Defendants admit that these actions will be subject to transfer and consolidation for pretrial proceedings. Except as otherwise admitted herein, Defendants deny the allegations of this paragraph.

3. Answering paragraph 3, Defendants have insufficient information or knowledge to form a belief as to the truth of the allegations contained therein, and therefore deny the same.

4. Answering paragraph 4, Defendants have insufficient information or knowledge to form a belief as to the truth of the allegations contained therein, and therefore deny the same.

5. Answering paragraph 5, Defendants have insufficient information or knowledge to form a belief as to the truth of the allegations contained therein, and therefore deny the same.

6. Answering paragraph 6, Defendants state that the allegations contained therein assert legal conclusions to which no response is required. To the extent a response is deemed required, Defendants admit that it Pfizer a Delaware corporation with its principal place of business in New York, and that it acquired Pharmacia Corporation on April 16, 2003. Defendants further admit that, at times, they marketed and co-promoted Celecoxib under the name Celebrex® throughout the United States, including Minnesota. Except as admitted herein, Defendants deny the remaining allegations of this paragraph.

7. Answering paragraph 7, Defendants admit that Searle is a wholly-owned subsidiary of Pharmacia, which is in turn a wholly-owned subsidiary of Pfizer. Searle is a Delaware limited liability company with its principal place of business in Illinois. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, and distributed Celebrex® in the United States to be prescribed by health care providers who are authorized by law to

prescribe drugs in accordance with their approval by the FDA. Except as admitted herein, Defendants deny the allegations of this paragraph.

8. Answering paragraph 8, Defendants admit that Pharmacia is a corporation existing under the laws of the State of Delaware with its principal place of business in New Jersey. Defendants further admit that Pharmacia & Upjohn Company LLS merged with Monsanto Co. in April 2000 to form Pharmacia. Defendants also admit that Pharmacia is a wholly-owned subsidiary of Pfizer. Defendants admit that, during certain periods of time, Pharmacia marketed the prescription drug Celebrex® in the United States for the indications set forth in the FDA-approved package inserts, as permitted by law. Except as admitted herein, Defendants deny the allegations of this paragraph.

9. Answering paragraph 9, Defendants admit that Celebrex® was developed by Searle and admit that on December 31, 1998 the FDA granted approval of an NDA submitted by Searle on June 29, 1998. Defendants also admit that, during certain periods of time, Searle and Pfizer marketed Celebrex®. Defendants admit that in April 2003, Pfizer acquired Pharmacia. Except as admitted herein, Defendants deny the allegations of this paragraph.

10. Answering paragraph 10, Defendants admit that Pfizer, at certain times, marketed and co-promoted Celebrex®, that Pharmacia, at certain times, marketed Celebrex®, and that Searle, at certain times, marketed and distributed Celebrex®. Defendants deny making any misrepresentations or omissions regarding the safety and effectiveness of Celebrex®, deny any wrongdoing, and state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Answering further, Defendants state that Celebrex® is and was safe and effective when used

in accordance with its FDA-approved prescribing information. Except as stated herein, Defendants deny the allegations of this paragraph.

11. Answering paragraph 11, Defendants state that the allegations contained therein assert legal conclusions to which no response is required. To the extent a response is deemed required, Defendants deny the allegations contained therein.

12. Answering paragraph 12, Defendants state that the allegations contained therein assert legal conclusions to which no response is required. To the extent a response is deemed required, Defendants admit that this Court has jurisdiction pursuant to 28 U.S.C. § 1332 (diversity jurisdiction) in that Plaintiffs allege that the amount in controversy exceeds $75,000.00 and that they are citizens of a different state than Defendants.

13. Answering paragraph 13, Defendants state that the allegations contained therein assert legal conclusions to which no response is required. To the extent a response is deemed required, Defendants state that referenced case law speaks for itself, and Defendants deny any attempt by Plaintiffs to characterize it.

14. Answering paragraph 14, Defendants state that the allegations contained therein assert legal conclusions to which no response is required. To the extent a response is deemed required, Defendants state that referenced case law speaks for itself, and Defendants deny any attempt by Plaintiffs to characterize it.

15. Answering paragraph 15, Defendants state that the allegations contained therein assert legal conclusions to which no response is required. To the extent a response is deemed required, Defendants deny the allegations contained in this paragraph and Defendants further allege that if Plaintiffs are citizens and resident of the States of Tennessee and Kansas, this action is subject to change of venue pursuant to 28 U.S.C. § 1404.

16. Answering paragraph 16, Defendants state that the allegations contained therein assert legal conclusions to which no response is required. To the extent a response is deemed required, Defendants state that they lacks sufficient knowledge and information to form a belief as to the meaning of "all times relevant herein," but admit that, at times, Pfizer marketed and co-promoted Celebrex®, Pharmacia marketed Celebrex®, and Searle marketed and distributed Celebrex® throughout the United States, including Minnesota. Defendants deny that they made material misrepresentations and breaches of warranty. Except as otherwise admitted herein, Defendants deny the allegations of this paragraph.

17. Answering paragraph 17, Defendants admit that Celebrex® is among a class of medications called nonsteroidal anti-inflammatory drugs ("NSAIDs"). Except as otherwise admitted herein, Defendants are without sufficient information or knowledge to form a belief as to the truth of the allegations contained therein, and therefore deny the same.

18. Answering paragraph 18, Defendants state that the allegations are not directed to Defendants, and therefore, no response is required. To the extent a response is deemed required, Defendants state that as stated in the package insert approved by the FDA, Defendants admit that Celebrex® is approved by the FDA for the following indications:

(1) Relief of the signs and symptoms of osteoarthritis;

(2) Relief of the signs and symptoms of rheumatoid arthritis;

(3) The management of acute pain in adults;

(4) Treatment of primary dysmenorrhea;

(5) To reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic surveillance surgery); and

(6) Relief of signs and symptoms of ankylosing spondylitis.

Defendants further admit that, as stated in the FDA-approved labeling for Celebrex®, "[t]he mechanism of action of Celebrex® is believed to be due to the inhibition of prostaglandin synthesis, primarily in inhibition of cyclooxygenase-2 (Cox-2), and at therapeutic concentrations in humans, Celebrex® does not inhibit the cyclooxygenase-1 (Cox-1) isoenzyme." Except as admitted herein, Defendants deny the allegations of this paragraph.

19. Answering paragraph 19, the allegations are not directed to Defendants, and therefore, no response is required. To the extent a response is deemed required, Defendants incorporate their answer to paragraph 18 as if fully restated herein. Except as admitted herein, Defendants deny the allegations of this paragraph.

20. Answering paragraph 20, the allegations are not directed to Defendants, and therefore, no response is required. To the extent a response is deemed required, Defendants incorporate their answer to paragraph 18 as if fully restated herein. Except as admitted herein, Defendants deny the allegations of this paragraph.

21. Answering paragraph 21, the allegations are not directed to Defendants, and therefore, no response is required. To the extent a response is deemed required, Defendants incorporate their answer to paragraph 18 as if fully restated herein. Except as admitted herein, Defendants deny the allegations of this paragraph.

22. Answering paragraph 22, Defendants deny any wrongdoing and deny the allegations contained therein.

23. Answering paragraph 23, Defendants admit that on December 31, 1998, the FDA granted approval of an NDA submitted by Searle on June 29, 1998. Defendants further state that as stated in the package insert approved by the FDA, Defendants admit that Celebrex® is approved by the FDA for the following indications:

(1) Relief of the signs and symptoms of osteoarthritis;

(2) Relief of the signs and symptoms of rheumatoid arthritis;

(3) The management of acute pain in adults;

(4) Treatment of primary dysmenorrhea;

(5) To reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic surveillance surgery); and

(6) Relief of signs and symptoms of ankylosing spondylitis.

Defendants further admit that, as stated in the FDA-approved labeling for Celebrex®, "[t]he mechanism of action of Celebrex® is believed to be due to the inhibition of prostaglandin synthesis, primarily in inhibition of cyclooxygenase-2 (Cox-2), and at therapeutic concentrations in humans, Celebrex® does not inhibit the cyclooxygenase-1 (Cox-1) isoenzyme." Except as admitted herein, Defendants deny the allegations of paragraph 27.

24. Answering paragraph 24, Defendants admit that, at times, they marketed and co-promoted Celebrex® throughout the United States. Answering further, Defendants state that Celebrex® is and was safe and effective when used in accordance with its FDA-approved prescribing information and that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny that they made any misrepresentations regarding the safety and effectiveness of Celebrex® and deny any wrongdoing. Except as otherwise admitted herein, Defendants deny the allegations of this paragraph.

25. Answering paragraph 25, Defendants refer to Dr. Eric Topol's August 22, 2001 article in the *Journal of the American Medical Association*, which speaks for itself, and any attempt to characterize it is denied. Defendants state that the potential side effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law, and that Celebrex® is and was safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the remaining allegations contained in this paragraph.

26. Answering paragraph 26, Defendants refer to Dr. Garrett Fitzgerald's October 21, 2005 editorial in *The New England Journal of Medicine*, which speaks for itself, and any attempt to characterize it is denies. Defendants state that Celebrex® is and was safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the remaining allegations contained in this paragraph.

27. Answering paragraph 27, Defendants state that referenced agency document speaks for itself and Defendants deny any attempt by Plaintiffs to characterize it. Defendants deny the remaining allegations of this paragraph.

28. Answering paragraph 28, Defendants state that Plaintiffs fail to provide proper context for the allegations concerning the referenced "studies", and therefore Defendants are without sufficient information to confirm or deny the allegations contained in this paragraph, and Defendants therefore deny the same. Defendants specifically deny any wrongdoing and deny the remaining allegations contained in this paragraph.

29. Answering paragraph 29, Defendants state that Plaintiffs fail to provide proper context for the allegations concerning the referenced "studies", and therefore Defendants are

without sufficient information to confirm or deny the allegations contained in this paragraph, and Defendants therefore deny the same. Except as stated herein, Defendants deny any wrongdoing and deny the allegations contained in this paragraph.

30. Answering paragraph 30, Defendants admit that a Medical Officer Review dated September 20, 2000 was completed by the FDA for the supplemental NDA submitted for Celebrex®. Defendants assert that the Medical Officer Review and the referenced CLASS study speak for themselves and any attempt to characterize them is denied. Except as admitted herein, Defendants deny the remaining allegations contained in this paragraph.

31. Answering paragraph 31, Defendants refer to Dr. F. Silverstein, *et al.*'s September 13, 2000 article in the *Journal of the American Medical Association*, which speaks for itself, and any attempt to characterize it is denied.

32. Answering paragraph 32, Defendants state that the CLASS study speaks for itself and Defendants deny any attempt by Plaintiffs to characterize it. Defendants deny making any misrepresentations or omissions regarding Celebrex®, deny any wrongdoing, and deny the allegations contained in this paragraph.

33. Answering paragraph 33, Defendants state that referenced agency documents and CLASS study speak for themselves and Defendants deny any attempt by Plaintiffs to characterize them. Defendants incorporate their answer to paragraph 32 as if fully stated herein. Defendants deny the remaining allegations of this paragraph.

34. Answering paragraph 34, Defendants state that referenced study speaks for itself and Defendants deny any attempt by Plaintiffs to characterize it. Defendants deny the remaining allegations of this paragraph.

35. Answering paragraph 35, Defendants state that referenced study and articles speak for themselves and Defendants deny any attempt by Plaintiffs to characterize them. Defendants deny the remaining allegations of this paragraph.

36. Answering paragraph 36, Defendants refer to the August 5, 2001 article in the *Washington Post*, which speaks for itself and any attempt to characterize it is denied. Defendants specifically deny making any misrepresentations and deny the remaining allegations of this paragraph.

37. Answering paragraph 37, Defendants refer to the August 5, 2001 article in the *Washington Post*, which speaks for itself and any attempt to characterize it is denied. Defendants specifically deny making any misrepresentations and deny the remaining allegations of this paragraph.

38. Answering paragraph 38, Defendants state that referenced studies and publications speak for themselves and Defendants deny any attempt by Plaintiffs to characterize them. Defendants deny making any misrepresentations and deny the remaining allegations of this paragraph.

39. Answering paragraph 39, Defendants state that referenced agency document speaks for itself and Defendants deny any attempt by Plaintiffs to characterize it. Defendants deny the remaining allegations of this paragraph.

40. Answering paragraph 40, Plaintiffs fail to provide proper context for the allegations concerning "Public Citizen" contained in paragraph 45, and therefore Defendants are without sufficient information or knowledge to form a belief as to the truth of the allegations contained therein, and therefore deny the same. Defendants deny the remaining allegations of this paragraph.

41. Answering paragraph 41, Defendants state that the referenced article speaks for itself and Defendants deny any attempt by Plaintiffs to characterize it. Defendants deny the remaining allegations of this paragraph.

42. Answering paragraph 42, Defendants state that the allegations contained therein assert legal conclusions to which no response is required. Defendants further state that Plaintiffs fail to provide proper context for the allegations concerning "Public Citizen" contained in this paragraph, and therefore Defendants are without sufficient information or knowledge to form a belief as to the truth of the allegations contained therein, and therefore deny the same. Defendants state that referenced CLASS study speaks for itself and Defendants deny any attempt by Plaintiffs to characterize it. Defendants deny the remaining allegations contained in this paragraph.

43. Answering paragraph 43, Defendants state that referenced study speaks for itself and Defendants deny any attempt by Plaintiffs to characterize it.

44. Answering paragraph 44, Defendants state that referenced studies and article speak for themselves and Defendants deny any attempt by Plaintiffs to characterize it. Defendants deny the remaining allegations of this paragraph.

45. Answering paragraph 45, Defendants state that referenced study and article speak for themselves and Defendants deny any attempt by Plaintiffs to characterize them. Defendants deny the remaining allegations of this paragraph.

46. Answering paragraph 46, Defendants state that referenced agency document speaks for itself and Defendants deny any attempt by Plaintiffs to characterize it. Defendants deny the remaining allegations of this paragraph.

47. Answering paragraph 47, Defendants state that referenced agency document and study speak for themselves and Defendants deny any attempt by Plaintiffs to characterize it. Defendants deny the remaining allegations of this paragraph.

48. Answering paragraph 48, Defendants state that referenced trial speaks for itself and Defendants deny any attempt by Plaintiffs to characterize it. Defendants deny the remaining allegations of this paragraph.

49. Answering paragraph 49, Defendants state that referenced article speaks for itself and Defendants deny any attempt by Plaintiffs to characterize it. Defendants further answer that Plaintiffs fail to provide proper context for the allegations concerning "Public Citizen" contained in this paragraph, and therefore Defendants are without sufficient information or knowledge to form a belief as to the truth of the allegations contained therein, and therefore deny the same. Defendants deny the remaining allegations of this paragraph.

50. Answering paragraph 50, Defendants state that referenced studies speak for themselves and Defendants deny any attempt by Plaintiffs to characterize them. Defendants deny the remaining allegations of this paragraph.

51. Answering paragraph 51, Defendants state that referenced study and Medical Officer Review speak for themselves and Defendants deny any attempt by Plaintiffs to characterize them. Defendants deny the remaining allegations of this paragraph.

52. Answering paragraph 52, Defendants state that referenced study speaks for itself and Defendants deny any attempt by Plaintiffs to characterize it. Defendants deny the remaining allegations of this paragraph.

53. Answering paragraph 53, Defendants state that referenced study speaks for itself and Defendants deny any attempt by Plaintiffs to characterize it. Defendants deny the remaining allegations of this paragraph.

54. Answering paragraph 54, Defendants state that the allegations related to Merck are unrelated to Defendants and therefore no response is required. To the extent a response is deemed required, Defendants state that the referenced study and article speak for themselves and Defendants deny any attempt by Plaintiffs to characterize them. Defendants deny the remaining allegations of this paragraph.

55. Answering paragraph 55, Defendants deny the allegations contained therein.

56. Answering paragraph 56, Defendants state that referenced article speaks for itself and Defendants deny any attempt by Plaintiffs to characterize it. Defendants deny the remaining allegations of this paragraph.

57. Answering paragraph 57, Defendants state that the referenced article speaks for itself and Defendants deny any attempt by Plaintiffs to characterize it. Defendants deny the remaining allegations of this paragraph.

58. Answering paragraph 58, Defendants state that Plaintiffs' allegations, including but not limited to the allegations regarding "scientific data," "testing," and "studies," are vague and ambiguous and, as a result, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations. Defendants deny the remaining allegations of this paragraph.

59. Answering paragraph 59, Defendants deny the allegations contained therein.

60. Answering paragraph 650, Defendants state that Celebrex® is and was safe and effective when used in accordance with its FDA-approved prescribing information.

Answering further, Defendants deny any wrongdoing and deny the allegations contained in this paragraph.

61. Answering paragraph 61, Defendants deny any wrongdoing and deny the allegations contained therein.

62. Answering paragraph 62, Defendants state that Celebrex® is and was safe and effective when used in accordance with its FDA-approved prescribing information and that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Answering further, Defendants admit that, at times, Pfizer marketed and co-promoted Celebrex®, Pharmacia marketed Celebrex®, and Searle marketed and distributed Celebrex®. Defendants deny any wrongdoing and except as admitted herein, deny the allegations contained in this paragraph.

63. Answering paragraph 63, Defendants state that Celebrex® is and was safe and effective when used in accordance with its FDA-approved prescribing information. Answering further, Defendants deny that their actions were fraudulent or misleading and deny the allegations contained therein and specifically deny that Celebrex® is or was defective of unreasonably dangerous. Defendants deny the remaining allegations contained in this paragraph.

64. Answering paragraph 64, Defendants state that referenced agency documents speak for themselves and Defendants deny any attempt by Plaintiffs to characterize them. Defendants deny that their actions were fraudulent and deny the remaining allegations of this paragraph.

65. Answering paragraph 65, Defendants state that referenced agency document speaks for itself and Defendants deny any attempt by Plaintiffs to characterize it.

66. Answering paragraph 66, Defendants state that referenced article speaks for itself and Defendants deny any attempt by Plaintiffs to characterize it. As to the remaining allegations, Defendants deny making any misrepresentations and deny the remaining allegations of this paragraph.

67. Answering paragraph 67, Defendants state that referenced agency document speaks for itself and Defendants deny any attempt by Plaintiffs to characterize it.

68. Answering paragraph 68, Defendants lack sufficient knowledge and information to form a belief as to the meaning of "all times relevant herein," but admit that, at times, Pfizer marketed and co-promoted Celebrex®, Pharmacia marketed Celebrex®, and Searle marketed and distributed Celebrex®. Except as otherwise admitted herein, Defendants deny the allegation of this paragraph.

69. Answering paragraph 69, Defendants admit that, at times, Pfizer marketed and co-promoted Celebrex®, Pharmacia marketed Celebrex®, and Searle marketed and distributed Celebrex® throughout the United States. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Answering further, Defendants state that Celebrex® is and was safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny making any misrepresentations or omissions regarding the safety and effectiveness of Celebrex®. Except as otherwise admitted or stated herein, Defendants deny the allegation of this paragraph.

70. Answering paragraph 70, Defendants deny any wrongdoing and state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants further state that Celebrex® is and was safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the remaining allegations of this paragraph.

71. Answering paragraph 71, Defendants admit that, at times, they Pfizer marketed and co-promoted Celebrex®, Pharmacia marketed Celebrex®, and Searle marketed and distributed Celebrex®. Defendants deny the remaining allegations of this paragraph or are without sufficient information or knowledge to form a belief as to the truth of the allegations contained therein, and therefore deny the same.

72. Answering paragraph 72, Defendants state that Celebrex® is and was safe and effective when used in accordance with its FDA-approved prescribing information. Except as stated herein, Defendants deny the allegations of this paragraph.

73. Answering paragraph 73, Defendants deny any wrongdoing and state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Answering further, Defendants state that Celebrex® is and was safe and effective when used in accordance with its FDA-approved prescribing information. Except as stated herein, Defendants deny the allegations of this paragraph.

74. Answering paragraph 74, Defendants state that Celebrex® is and was safe and effective when used in accordance with its FDA-approved prescribing information and that the potential effects of Celebrex® were and are adequately described in its FDA-approved

prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny making any misrepresentations or omissions regarding the safety and effectiveness of Celebrex®, and deny the remaining allegations of this paragraph.

75. Answering paragraph 75, Defendants admit that, at times, Pfizer marketed and co-promoted Celebrex®, Pharmacia marketed Celebrex®, and Searle marketed and distributed Celebrex®. Except as admitted herein, Defendants deny the allegations of this paragraph.

76. Answering paragraph 76, Defendants state that Celebrex® is and was safe and effective when used in accordance with its FDA-approved prescribing information and that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Except as stated herein, Defendants deny the allegations of this paragraph.

77. Answering paragraph 77, Defendants state that the allegations contained therein assert legal conclusions to which no response is required. To the extent a response is deemed required, Defendants deny any wrongdoing and deny concealing or omitting material information. Defendants deny the remaining allegations of this paragraph.

78. Answering paragraph 78, Defendants deny the allegations contained therein.

79. Answering paragraph 79, Defendants deny any wrongdoing and state that Celebrex® is and was safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all

times adequate and comported with applicable standards of care and law. Defendants specifically deny that Celebrex® is or was defective of unreasonably dangerous and deny the remaining allegations of this paragraph.

80. Answering paragraph 80, Defendants state that Celebrex® is and was safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny any wrongdoing and except as stated herein deny the remaining allegations of this paragraph.

81. Answering paragraph 81, Defendants state that the allegations contained therein assert legal conclusions to which no response is required. To the extent a response is deemed required, Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants further state that Celebrex® is and was safe and effective when used in accordance with its FDA-approved prescribing information. Except as stated herein, Defendants deny the allegations of this paragraph.

82. Answering paragraph 82, Defendants deny the allegations contained therein.

83. Answering paragraph 83, Defendants state that the allegations contained therein assert legal conclusions to which no response is required. To the extent a response is deemed required, Defendants admit that, at times, Pfizer marketed and co-promoted Celebrex®, Pharmacia marketed Celebrex®, and Searle marketed and distributed Celebrex®. Answering further, Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law, and that Celebrex® is

and was safe and effective when used in accordance with its FDA-approved prescribing information. Except as stated herein, Defendants deny the allegations of this paragraph.

84. Answering paragraph 84, Defendants are without sufficient information or knowledge to form a belief as to the truth of the allegations contained therein relating to Plaintiff Paula Deaton's prescription and consumption of Celebrex®. Defendants deny that Plaintiffs were injured as a result of using Celebrex®. Defendants state that Celebrex® is and was safe and effective when used in accordance with its FDA-approved prescribing information.

85. Answering paragraph 85, Defendants are without sufficient information or knowledge to form a belief as to the truth of the allegations contained therein relating to Plaintiff Paula Deaton's prescription and consumption of Celebrex®. Defendants deny that plaintiffs were injured as a result of using Celebrex®. Defendants state that Celebrex® is and was safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law.

86. Answering paragraph 86, Defendants deny that plaintiffs were injured as a result of using Celebrex®. Defendants state that Celebrex® is and was safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny any wrongdoing and deny the allegations contained therein.

87. Answering paragraph 87, Defendants are without sufficient information or knowledge to form a belief as to the truth of the allegations contained therein relating to Plaintiff Donald Shaft's prescription and consumption of Celebrex®. Defendants deny that

Plaintiffs were injured as a result of using Celebrex®. Defendants state that Celebrex® is and was safe and effective when used in accordance with its FDA-approved prescribing information.

88. Answering paragraph 88, Defendants are without sufficient information or knowledge to form a belief as to the truth of the allegations contained therein relating to Plaintiff Donald Shaft's prescription and consumption of Celebrex®. Defendants deny that plaintiffs were injured as a result of using Celebrex®. Defendants state that Celebrex® is and was safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law.

89. Answering paragraph 89, Defendants deny that plaintiffs were injured as a result of using Celebrex®. Defendants state that Celebrex® is and was safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny any wrongdoing and deny the allegations contained therein.

90. Answering paragraph 90, Defendants incorporate by reference all previous paragraphs as though fully set forth herein.

91. Answering paragraph 91, Defendants admit that, at times, Pfizer marketed and co-promoted Celebrex®. Except as stated herein Defendants deny the allegations of this paragraph.

92. Answering paragraph 92, Defendants state that the allegations contained therein assert legal conclusions to which no response is required. To the extent a response is deemed required, Defendants deny that Celebrex® is or was defective or unreasonably

dangerous and state that Celebrex® is and was safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the remaining allegations of this paragraph.

93. Answering paragraph 93, Defendants deny that Celebrex® is or was defective or unreasonably dangerous and deny the remaining allegations of this paragraph.

94. Answering paragraph 94, Defendants state that in the ordinary case, Celebrex® was expected to reach consumers without substantial change from the time of sale. However, Defendants are without sufficient information or knowledge to form a belief as to the truth of the allegations contained in this paragraph, and therefore deny the same.

95. Answering paragraph 95, Defendants deny that Plaintiffs were injured as a result of using Celebrex® and deny the remaining allegations of this paragraph.

96. Answering paragraph 96, Defendants deny that Plaintiffs are entitled to the relief sought therein.

97. Answering paragraph 97, Defendants incorporate by reference all previous paragraphs as though fully set forth herein.

98. Answering paragraph 98, Defendants state that the allegations contained therein assert legal conclusions to which no response is required. To the extent a response is deemed required, Defendants admit that, at times, Pfizer marketed and co-promoted Celebrex®, Pharmacia marketed Celebrex®, and Searle marketed and distributed Celebrex®.

99. Answering paragraph 99, Defendants deny that they made any statements or representations to Plaintiffs or to others that might be implied by law as warranties regarding Celebrex®, and deny the allegations of this paragraph.

100. Answering paragraph 100, Defendants deny that they made any implied warranties regarding Celebrex® and state that Celebrex® is and was safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the remaining allegations of this paragraph.

101. Answering paragraph 101, Defendants deny the allegations contained therein.

102. Answering paragraph 102, Defendants deny that they made any implied warranties regarding Celebrex®, deny that they breached any such warranty, deny that Plaintiffs were injured as a result of using Celebrex®, and deny the remaining allegations contained in this paragraph.

103. Answering paragraph 103, Defendants deny that Plaintiffs are entitled to the relief sought therein.

104. Answering paragraph 104, Defendants incorporate by reference all previous paragraphs as though fully set forth herein.

105. Answering paragraph 105, Defendants state that the allegations contained therein assert legal conclusions to which no response is required. To the extent a response is deemed required, Defendants admit that, at times, Pfizer marketed and co-promoted Celebrex®, Pharmacia marketed Celebrex®, and Searle marketed and distributed Celebrex®. Except as otherwise admitted herein, Defendants deny the allegations contained in this paragraph.

106. Answering paragraph 106, Defendants deny the allegations contained therein.

107. Answering paragraph 107, Defendants deny that they made any implied warranties regarding Celebrex® and deny the allegations of this paragraph.

108. Answering paragraph 108, Defendants state that Celebrex® is and was safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the remaining allegations of this paragraph, including all subpart.

109. Answering paragraph 109, Defendants state that Celebrex® is and was safe and effective when used in accordance with its FDA-approved prescribing information. Answering further, Defendants deny that they made any implied warranties regarding Celebrex®, deny that they breached any such warranty, and deny the remaining allegations contained in this paragraph.

110. Answering paragraph 110, Defendants deny the allegations contained therein.

111. Answering paragraph 111, Defendants deny that they made any implied warranties regarding Celebrex®, deny that they breached any such warranty, deny that Plaintiffs were injured as a result of using Celebrex®, and deny the remaining allegations contained in this paragraph.

112. Answering paragraph 112, Defendants deny that Plaintiffs are entitled to the relief sought therein.

113. Answering paragraph 113, Defendants incorporate by reference all previous paragraphs as though fully set forth herein.

114. Answering paragraph 114, Defendants deny that they made any express warranties regarding Celebrex® and deny that they made any statements or representations to Plaintiffs or to others that might be implied by law as warranties regarding Celebrex®. Defendants further state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Celebrex® is and was safe and

effective when used in accordance with its FDA-approved prescribing information. Defendants deny any wrongdoing and deny the remaining allegations of this paragraph, including all subparts.

115. Answering paragraph 115, Defendants deny that Plaintiffs are entitled to the relief sought therein.

116. Answering paragraph 116, Defendants incorporate by reference all previous paragraphs as though fully set forth herein.

117. Answering paragraph 117, Defendants state that the allegations contained therein assert legal conclusions to which no response is required. To the extent a response is deemed required Defendants admit that, at times, Pfizer marketed and co-promoted Celebrex®, Pharmacia marketed Celebrex®, and Searle marketed and distributed Celebrex®. Answering further, Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Celebrex® is and was safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny any wrongdoing and deny the remaining allegations of this paragraph, including all subparts.

118. Answering paragraph 118, Defendants deny that Plaintiffs were injured as a result of using Celebrex® and deny the remaining allegations of this paragraph.

119. Answering paragraph 119, Defendants deny that Plaintiffs are entitled to the relief sought therein.

120. Defendants deny that Plaintiffs are entitled to the relief demanded in their Complaint.

121. Defendants state that the allegations contained in Plaintiffs' Demand for Jury Trial assert legal conclusions to which no response is required.

AFFIRMATIVE DEFENSES

Discovery and investigation may reveal that one or more of the following defenses should be available to Defendants in this matter. Defendants therefore assert the following defenses in order to preserve the right to assert them. Upon completion of discovery, if the facts warrant, Defendants will withdraw any of these defenses as may be appropriate.

First Defense

1. The Complaint fails to state a claim upon which relief can be granted.

Second Defense

2. The claims asserted in the Complaint are barred, in whole or part, by the applicable statue(s) of limitations and/or repose, or by the applicable doctrines of laches, waiver, and/or estoppel.

Third Defense

3. The claims asserted in the Complaint are barred, in whole or part, because Plaintiffs lack standing and/or capacity to bring such claims.

Fourth Defense

4. The claim(s) for breach of warranty asserted in the Complaint is (are) barred by Plaintiffs' failure to give timely notice.

Fifth Defense

5. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiffs did not incur any ascertainable loss as a result of Defendants' conduct.

Sixth Defense

6. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiffs have not suffered injuries or a significantly increased risk of contracting serious latent diseases or injuries as a result of Celebrex® use.

Seventh Defense

7. The claims asserted in the Complaint are barred, in whole or in part, by Plaintiffs' failure to exercise reasonable care and diligence to mitigate their damages, if any.

Eighth Defense

8. Plaintiffs' losses, if any, are subject to an offset for benefits received by Plaintiffs resulting from their alleged use of Celebrex®.

Ninth Defense

9. If Plaintiffs sustained any damages as alleged, such damages arose from, and were caused by, risks, hazards, and dangers knowingly assumed by Plaintiffs. Plaintiffs' recovery accordingly is barred or should be reduced by their assumption of the risk.

Tenth Defense

10. Defendants are entitled to credit for any settlement of claims for alleged injuries and damages made by Plaintiffs with any other defendant, person, or entity.

Eleventh Defense

11. This Court should abstain from adjudicating Plaintiffs' claims relating to warnings and labeling in deference to the interpretation of regulations relating to prescription drug labeling by the FDA.

Twelfth Defense

12. The claims asserted in the Complaint are barred, in whole or in part, by the doctrine of abstention, in that the common law gives deference to discretionary actions by the FDA under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 et seq.

Thirteenth Defense

13. The claims asserted in the Complaint are barred, in whole or in part, by the doctrines of primary jurisdiction and exhaustion of administrative remedies, because the FDA has exclusive or primary jurisdiction over the matters asserted in the Petition.

Fourteenth Defense

14. The claims asserted in the Complaint are barred, in whole or in part, because the products are comprehensively regulated by the FDA pursuant to the FDCA, and regulations promulgated thereunder, and Plaintiffs' claims conflict with the FDCA, with the regulations promulgated by the FDA to implement the FDCA, with the purposes and objectives of the FDCA and the FDA's implementing regulations, and with the specific determinations by the FDA specifying the language that should be used in the labeling accompanying the products. Accordingly, Plaintiffs' claims are preempted by the Supremacy Clause of the Constitution of the United States, Article VI, clause 2, and the laws of the United States, including but not limited to the FDCA and the regulations promulgated thereunder. Alternatively Defendants are entitled to a presumption that Celebrex® is not defective or unreasonably dangerous.

Fifteenth Defense

15. The prescription drug Celebrex® complied with the then-applicable product safety regulations promulgated by the FDA.

Sixteenth Defense

16. The claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards, and regulations established, adopted, promulgated, or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

Seventeenth Defense

17. To the extent the claims asserted in the Complaint are based on a theory providing for liability without proof of causation, the claims violate Defendants' rights under the Constitution of the United States and analogous provisions of the applicable states' constitutions.

Eighteenth Defense

18. The claims asserted in the Complaint are barred, in whole or in part, by the learned intermediary doctrine.

Nineteenth Defense

19. If Plaintiffs sustained any damages as alleged, said damages resulted from an intervening or superseding cause and/or causes, and any act or omission on the part of Defendants was not the proximate and/or competent producing cause of such alleged damages.

Twentieth Defense

20. If Plaintiffs sustained any damages as alleged, said damages were solely caused by the acts or omissions, abuse or misuse, negligence, or fault, of third persons or parties over whom Defendants had no control or right to control and whose actions are not, therefore, imputable to Defendants.

Twenty-first Defense

21. If Plaintiffs sustained any damages as alleged, said damages were directly and proximately caused by the negligence, carelessness, or fault of the Plaintiffs, whose comparative negligence or fault is sufficient to bar these claims, or to proportionately reduce Plaintiffs' recovery.

Twenty-second Defense

22. The claims asserted in the Complaint are barred as a matter of law pursuant to the Restatement (Third) of Torts: Product Liability §§ 6(c) and 6(d), as reasonable physicians knowing of the reasonably foreseeable risks and therapeutic benefits associated with Celebrex® would have prescribed and did prescribe Celebrex® to Plaintiffs, and Defendants provided reasonable instructions and/or warnings to prescribing physicians.

Twenty-third Defense

23. If Plaintiffs sustained any damages as alleged, said damages were directly and proximately caused by the negligence, carelessness, or fault of parties other than Defendants, whether named or unnamed in Plaintiffs' Complaint, over whom Defendants had no supervision or control, and for whose actions and omissions Defendants has no legal responsibility. Plaintiffs' recovery, if any, should therefore be apportioned in accordance with the applicable law.

Twenty-fourth Defense

24. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiffs would have taken the product even if the product labeling contained the information Plaintiffs contends should have been provided.

Twenty-fifth Defense

25. The claims asserted in the Complaint are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the product, was not false or misleading, and therefore constitute protected commercial speech under the applicable provisions of the Constitution of the United States.

Twenty-sixth Defense

26. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiffs lack an adequate scientific basis to demonstrate any resulting harm or increased risk of future harm as a result of Plaintiffs' alleged Celebrex® use.

Twenty-seventh Defense

27. The claims asserted in the Complaint are barred, in whole or in part, because the product was not unreasonably dangerous or defective, was suitable for the purpose for which it was intended, and was marketed with adequate and sufficient warnings.

Twenty-eighth Defense

28. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® possesses no characteristic which renders it unreasonably dangerous in a reasonably anticipated use by an individual.

Twenty-ninth Defense

29. The claims asserted in the Complaint are barred, in whole or in part, because the utility of Celebrex® outweighs the alleged risk.

Thirtieth Defense

30. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® was designed, tested, manufactured, and labeled in accordance with state-of-the-art and industry standards existing at the time of sale.

Thirty-first Defense

31. The methods, standards, and techniques utilized with respect to the manufacture, testing, design, and marketing of Celebrex®, if any, including adequate warnings and instructions with respect to the product's use included in the product's package insert and other literature, conformed to the generally recognized, reasonably available and reliable state of the knowledge at the time the product was designed, tested, manufactured, and marketed.

Thirty-second Defense

32. Plaintiffs' injuries, if any, were due to an allergic, idiosyncratic, or idiopathic reaction to Celebrex®, or by an unforeseeable illness, unavoidable acts, or preexisting condition without any negligence or culpable conduct by Defendants.

Thirty-third Defense

33. The claims asserted in the Complaint are barred, in whole or in part, because the products "provide net benefits for a class of patients" within the meaning of comment f to Section 6 of the Restatement (Third) of Torts: Products Liability.

Thirty-fourth Defense

34. The claims asserted in the Complaint are barred as a matter of law pursuant to the Restatement (Third) of Torts: Product Liability § 4, *et seq*., because Celebrex® complied with applicable product safety statutes and administrative regulations.

Thirty-fifth Defense

35. The claims asserted in the Complaint are barred as a matter of law pursuant to Restatement (Second) of Torts § 402A, comments j & k.

Thirty-sixth Defense

36. Plaintiffs' fraud-based claims, if any, are not stated with particularity as required by Rule 9 of the Federal Rules of Civil Procedure.

Thirty-seventh Defense

37. Defendants assert the defense of improper venue pursuant to 28 U.S.C. §§ 1404 and 1406.

Thirty-eighth Defense

38. Plaintiffs are improperly joined within the under Rule 20 of the Federal Rules of Civil Procedure.

Thirty-ninth Defense

39. To the extent that Tennessee or Kansas law applies, Defendants plead all of the above affirmative defenses as they exist under Tennessee or Kansas common law and the applicable sections of Tennessee or Kansas statutory law.

DEFENDANTS' REQUEST FOR JURY TRIAL

Defendants request a trial by jury on all issues triable.

DEFENDANTS' PRAYER FOR RELIEF

WHEREFORE, Defendants pray for relief from judgment from Plaintiffs as follows:

1. Plaintiffs take nothing by reason of their Complaint.

2. Defendants recover their costs and attorneys' fees incurred herein;

3. For a trial by jury on all issues so triable; and

4. For such further and other relief as the Court deems proper.

Dated: July 10, 2007

FAEGRE & BENSON LLP

s/Joseph M. Price

Joseph M. Price, # 88201
Davina ShaRik Carson, #0351726
2200 Wells Fargo Center
90 South Seventh Street
Minneapolis, MN 55402-3901
(612) 766-7000

ATTORNEYS FOR PFIZER INC., PHARMACIA CORPORATION, AND G.D. SEARLE LLC

fb.us.2166233.01

FILED

AUG 0 6 2007

RICHARD W. WIEKING
CLERK, U.S. DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

JUDICIAL PANEL ON
MULTIDISTRICT LITIGATION

JUN 25 2007

FILED
CLERK'S OFFICE

DOCKET NO. 1699

BEFORE THE JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE BEXTRA AND CELEBREX MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION

(SEE ATTACHED SCHEDULE)

CONDITIONAL TRANSFER ORDER (CTO-75)

On September 6, 2005, the Panel transferred 30 civil actions to the United States District Court for the Northern District of California for coordinated or consolidated pretrial proceedings pursuant to 28 U.S.C. § 1407. *See* 391 F.Supp.2d 1377 (J.P.M.L. 2005). Since that time, 1,119 additional actions have been transferred to the Northern District of California. With the consent of that court, all such actions have been assigned to the Honorable Charles R. Breyer.

It appears that the actions on this conditional transfer order involve questions of fact that are common to the actions previously transferred to the Northern District of California and assigned to Judge Breyer.

Pursuant to Rule 7.4 of the Rules of Procedure of the Judicial Panel on Multidistrict Litigation, 199 F.R.D. 425, 435-36 (2001), these actions are transferred under 28 U.S.C. § 1407 to the Northern District of California for the reasons stated in the order of September 6, 2005, and, with the consent of that court, assigned to the Honorable Charles R. Breyer.

This order does not become effective until it is filed in the Office of the Clerk of the United States District Court for the Northern District of California. The transmittal of this order to said Clerk shall be stayed 15 days from the entry thereof. If any party files a notice of opposition with the Clerk of the Panel within this 15-day period, the stay will be continued until further order of the Panel.

FOR THE PANEL:

Jeffery N. Lüthi
Clerk of the Panel

I hereby certify that the annexed instrument is a true and correct copy of the original on file in my office.
ATTEST:
RICHARD W. WIEKING
Clerk, U.S. District Court
Northern District of California
By _____ Deputy Clerk
Date 1-22-08

Inasmuch as no objection is pending at this time, the stay is lifted.

JUL 11 2007

CLERK'S OFFICE
JUDICIAL PANEL ON
MULTIDISTRICT LITIGATION

SCANNED
JAN 25 2008
U.S. DISTRICT COURT MPLS

SCHEDULE CTO-75 - TAG-ALONG ACTIONS
DOCKET NO. 1699
IN RE BEXTRA AND CELEBREX MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION

DIST. DIV. C.A.#	CASE CAPTION	
ALABAMA NORTHERN		
~~ALN 7 07-1100~~	~~Michael A. Allen, etc. v. Pfizer Inc., et al.~~	Opposed 7/10/07
ILLINOIS SOUTHERN		
~~ILS 3 07-428~~	~~David White, et al. v. Pfizer Inc., et al.~~	Opposed 7/10/07
~~ILS 3 07-429~~	~~John Wiese, et al. v. Pfizer Inc., et al.~~	Opposed 7/10/07
MINNESOTA		
MN 0 07-2355	Leon Hendrix v. Pfizer Inc., et al.	
MN 0 07-2800	Paula Deaton, et al. v. Pfizer Inc., et al.	
TEXAS SOUTHERN		
TXS 2 07-242	Laurine Kreitz, et al. v. Pfizer Inc., et al.	

OFFICE OF THE CLERK
UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

Richard W. Wieking
Clerk

450 Golden Gate Avenue
San Francisco, CA 94102
415.522.2000

January 22nd, 2008

District Court of Minnesota
300 South Fouth Street
Minneapolis, MN 55415

Re: MDL 05-1699 In re Bextra and Celebrex Marketing, Sales Practices and Products Liability Litigation

Title of Case(s)	Your Case Number(s)
Paula Deaton v. Pfizer Inc., et al.	C.A. No. 07-2800

Dear Clerk:

Enclosed is a certified copy of the order from the Judicial panel on Multidistrict Litigation transferring the above entitled action to the Northern District of California, San Francisco Division. The case has been assigned to the Honorable Charles R. Breyer for coordinated or consolidated pretrial processing pursuant to 28 USC §1407.

Please forward the **original record** and **a certified copy of the docket entries** in the case listed above along with the enclosed copy of this transmittal letter to:

United States District Court
Northern District of California
450 Golden Gate Avenue, P.O. Box 36060
San Francisco, CA 94102
Attn: Simone Voltz

If the case is an electronic case filing please do one of the following: 1) e-mail the PDF documents, as separate PDF files, including a PDF copy of the docket sheet to **SFmdl_clerk@cand.uscourts.gov**, 2) provide us with a temporary log in and a password to directly access your database and to expedite the downloading of the PDF files we need and/or require, or, 3) if you prefer, on a disc. We appreciate your prompt attention to this matter.

JAN [illegible]
CLERK US DIST COURT
MINNEAPOLIS MN

Sincerely yours,
Richard W. Wieking, Clerk

Simone Voltz

By: Simone Voltz
Deputy Clerk

Encl.

ATYADM, CLOSED, CV

U.S. District Court
U.S.District Court Minnesota (DMN)
CIVIL DOCKET FOR CASE #: 0:07-cv-02800-ADM-JSM

Deaton et al vs Pfizer et al DO NOT DOCKET. CASE HAS BEEN TRANSFERRED OUT.
Assigned to: Judge Ann D. Montgomery
Referred to: Magistrate Judge Janie S. Mayeron
Cause: 28:1332-pip-Diversity-Personal Injury, Product Liability

Date Filed: 06/13/2007
Jury Demand: Plaintiff
Nature of Suit: 365 Personal Inj. Prod. Liability
Jurisdiction: Diversity

Plaintiff

Paula Deaton represented by **Elizabeth-NA L. Dudley**
Not Admitted
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Mark-NA B. Hutton
Not Admitted
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Martha K Wivell
Attorney at Law
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ATTORNEY TO BE NOTICED

Plaintiff

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Mark-NA B. Hutton
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Martha K Wivell
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V.

Defendant

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ATTORNEY TO BE NOTICED

Defendant

Pharmacia Corporation

represented by **Davina ShaRik Carson**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Defendant

G. D. Searle LLC
formerly known as
G.D. Searle & Co.

represented by **Davina ShaRik Carson**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Joseph M Price
(See above for address)
ATTORNEY TO BE NOTICED

Date Filed	#	Docket Text
06/13/2007	1	COMPLAINT with Jury Demand against Pfizer, Inc., Pharmacia Corporation, and G. D. Searle LLC (Filing fee $ 350 receipt number 400-13903.) assigned to Judge Richard H. Kyle per Master List and referred to Magistrate Judge Arthur J. Boylan, filed by Paula Deaton, and Donald Shaft. (Attachments: # 1 Civil Cover Sheet)(GJS) (Entered: 06/14/2007)
06/13/2007		Summons Issued as to Pfizer, Inc., Pharmacia Corporation, and G. D.

		Searle LLC. (GJS) (Entered: 06/14/2007)
06/15/2007	2	DISQUALIFICATION AND ORDER FOR REASSIGNMENT. Case reassigned to Judge Ann D. Montgomery for all further proceedings. Judge Richard H. Kyle no longer assigned to case. The new case number is 07cv2800 ADM/AJB. Signed by Judge Richard H. Kyle on 6/15/07. (JME) (Entered: 06/15/2007)
06/15/2007	3	SUMMONS Returned Executed by Paula Deaton. Pfizer, Inc. served on 6/13/2007, answer due 7/3/2007. (Wivell, Martha) (Entered: 06/15/2007)
06/19/2007	4	ORDER OF RECUSAL. Magistrate Judge Arthur J. Boylan recused. Case reassigned to Magistrate Judge Janie S. Mayeron for all further proceedings. The new case number is 07cv2800 ADM/JSM. Signed by Magistrate Judge Arthur J. Boylan on 6/18/07. (JME) (Entered: 06/19/2007)
06/22/2007	5	SUMMONS Returned Executed by Paula Deaton, Donald Shaft. G. D. Searle LLC served on 6/14/2007, answer due 7/5/2007. (Wivell, Martha) (Entered: 06/22/2007)
06/22/2007	6	SUMMONS Returned Executed by Paula Deaton, Donald Shaft. Pharmacia Corporation served on 6/14/2007, answer due 7/5/2007. (Wivell, Martha) (Entered: 06/22/2007)
07/10/2007	7	ANSWER to Complaint with Jury Demand *and DEFENSES* by Pfizer, Inc., G. D. Searle LLC.(Price, Joseph) (Entered: 07/10/2007)
07/10/2007	8	RULE 7.1 DISCLOSURE STATEMENT by Pfizer, Inc., Pharmacia Corporation, G. D. Searle LLC that there is no such parent or publicly held corporation to report. (Price, Joseph) (Entered: 07/10/2007)
07/10/2007	9	CERTIFICATE OF SERVICE by Pfizer, Inc., Pharmacia Corporation, G. D. Searle LLC re 7 Answer to Complaint, 8 Rule 7.1 - Disclosure Statement (Price, Joseph) (Entered: 07/10/2007)
01/25/2008	10	CERTIFIED COPY OF CONDITIONAL TRANSFER ORDER (CTO-75), transferring case to the Northern District of California per MDL Panel for coordinated or consolidated pretrial proceedings. Case assigned to Judge Charles R Breyer. (kt) (Entered: 01/29/2008)
01/29/2008		NOTICE to Attorney: #07-2800 ADM/JSM has been transferred to the Northern District of California pursuant to CTO-75. (kt) (Entered: 01/29/2008)